Assessing the evidence-base and implementation factors associated with early detection /screening of oral cavity cancer in the primary care dental setting

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Abstract

Oral cavity cancer (OCC) is a public health problem, with approximately 355,000 new cases and over 177,000 deaths occurring globally per year. In comparison with many other cancers, 5-year survival rates for OCC are relatively poor and there has been limited improvement in these rates over the past few decades. Delay from first symptom to referral for diagnosis is a risk factor for advanced stage presentation and subsequent poorer survival. By contrast, the treatment of small, early-stage lesions is associated with reduced morbidity and mortality. The oral cavity has been described as a site which is relatively easy to examine, and it has therefore been proposed that improvement in outcomes should be possible through implementation of guidelines associated with the examination of the mouth and surrounding tissues for oral cancer and oral potentially malignant disorders (OPMDs), this process is described as a conventional oral examination (COE).

An initial review of the literature showed that although there have been a number of systematic reviews and numerous clinical guidelines on the topic of the COE, there has been limited consistency and insufficient evidence available to support clear practice. Uncertainties remain around a number of factors associated with the examination process including: a) the method of conducting the COE, b) the target population, i.e. high risk or universal approach, c) the frequency of the oral cancer examination procedure, and d) the extent to which adjunct tools are used. Additionally, there is some ambiguity and limited information available on the clinical practice and views of oral health care professionals (OHCPs) and patients around these issues and the barriers and facilitators to implementing the COE in the primary dental care setting.

This thesis describes three studies which were undertaken to try and address the identified gaps in the knowledge and evidence base. The first study was a systematic overview of systematic reviews and published clinical guidelines and aimed to identify best practice in relation to oral cavity cancer early detection/ screening. The themes explored were based on the four factors associated with the examination process which were outlined above. The findings were used to develop the subsequent two studies. The second study explored the findings of the systematic overview among OHCPs in dental primary care in Scotland and the Sultanate of Oman (the home country of the author of this thesis). Qualitative in-depth interviews were undertaken with the dental professionals to investigate current practice in relation to the COE process and to identify barriers and facilitators to

implementation. Analysis was performed using an up-to-date model of behaviour change – the Behaviour Change Wheel. The interviews also asked for views on the development of risk-based tools to facilitate the prevention and early detection of OCC. The third study was a qualitative survey of dental primary care patients from the two countries to explore their perceptions of the barriers and facilitators to a COE and to obtain their views on the acceptability of risk-based interventions.

The systematic overview found that while there was a lack of evidence per se on the effectiveness of opportunistic screening, the conclusions of the high quality systematic reviews and clinical guidelines broadly advocated this approach. The high quality systematic reviews tended to suggest that the COE was more effective in high prevalence populations and also when performed in high risk individuals (defined as those who use tobacco and consume alcohol). However, there was insufficient evidence to support only conducting a COE, or doing so in a more detailed and focused way, in high risk dental patients. There was limited evidence, but some clinical guideline support for a risk-based recall interval for conducting a COE, based on assessed oral cavity cancer risks (3-6 months for patients at high risk, and 1-2 years for those at low risk). There was no evidence for the effectiveness or role of adjunct technologies to support the COE in dental primary care for the early detection / screening of oral cavity cancer.

The qualitative studies found that COEs were generally performed by oral health care professionals during dental check-ups, although patients were often not aware of this procedure or that it was undertaken for early detection / screening of oral cavity cancer. There were some variations in clinical practice with regard to how COEs were performed in both Oman and Scotland and also on whether a general or targeted approach was adopted. Most OHCPs used a universal approach, while some targeted - based on age and behavioural risk factors. This perhaps reflects the inconclusive results of the systematic overview in this area. The frequency of patient recall was generally reported to be every six months in both countries, and this is broadly in agreement with the evidence base, although some guidance supports a risk-based approach. While some OHCPs supported more frequent recalls for higher risk patients, there was some reluctance to increasing the time between visits as it was perceived that low-risk patients might not receive optimal care. Many of the dental professionals considered a risk-prediction tool worthy of further exploration, but some concerns were expressed about feasibility, particularly in relation to resource issues. In general, patients indicated they would consider attending more

frequently (3-6 months) if identified as being in a high risk group. However, they were somewhat more reluctant to agree to attend less often if they were identified at low risk. Dental patients interviewed seemed, in general, to be happy to be assessed for their oral cancer risk. While the OHCPs were concerned about using the term “oral cancer”, many patients, particularly those in Scotland, did not seem to have a problem with it. Adjunct methods were not used by the OHCPs. However, rather than this practice always being based on knowledge of the evidence base, other barriers were also cited. In Oman this was reported to be due in part to a lack of availability of the technologies, while some in Scotland mentioned time and resource constraints. Some other differences in OHCP responses were found between the two countries, for example – restrictions in social opportunities to conduct a COE in Oman and variations in the reported barriers to the COE (lack of guidance and training in Oman, and time and remuneration issues in Scotland).

The commonalities and differences in identified barriers and facilitators between Oman and Scotland indicate opportunities to support implementation of best practice, elicited from the systematic overview, at both clinical and policy levels. Furthermore, research opportunities have been identified, for example, related to the development of a risk assessment tool to support the prevention and early detection of OCC in dental primary care. Such theory-based interventions at the clinical, policy and research levels have the potential for future impact on the morbidity and mortality from oral cancer in the community.

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Author's Declaration

Chapter three of this thesis was presented at the EADPH conference in Budapest, Hungary in 2016. The title of the presentation was:

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I declare that, except where explicit reference is made to the contribution of others, this dissertation is the result of my own work and has not been submitted for any other degree at the University of Glasgow or any other institution.

Signature

Printed name: Naeema Mohammed Saleh Al Bulushi

Abbreviations

Abbreviation	Long Form
ACS	American Cancer Society
ADA	American Dental Association
AHRQ	Agency for Healthcare Research and Quality
BDA	British Dental Association
BMI	Body Mass Index
COE	Conventional Oral Examination
FCTC	Framework Convention on Tobacco Control
GCC	Gulf Cooperation Council
GDC	General Dental Council
HNC	Head and Neck Cancer
HPV	Human Papilloma Virus
ICD-10	International Statistical Classification of Diseases and Related Health Problems 10th revision
ICD-O	International Classification of Diseases for Oncology
INHANCE	International Head and Neck Cancer Epidemiology
MOH	Ministry of Health
NCD	Non-Communicable Disease
NHS	National Health Services
NICE	National Institute for Clinical Excellence
NIH	National Institute Of Health
NSC	National Screening Committee
NSC	National Screening Committee
OCC	Oral Cavity Cancer

OPMD	Oral Potential Malignant Disorders
RCT	Randomised Controlled Trial
SDCEP	Scottish Dental Clinical Effectiveness Programme
SIGN	Scottish Intercollegiate Guidelines Network
SPH	Solutions for Public Health
UN	United Nations
US	United States
USPSTF	United States Preventive Services Task Force
WHO	World Health Organization

Chapter 1: Literature review

1.1 Introduction

The thesis focuses on evaluating the evidence in relation to the examination of a patient for oral cavity cancer and explores how best to support this practice in primary dental care. This chapter sets out the literature relevant to this topic area and provides a context for the chapters which follow. Initially, a brief overview of non-communicable diseases and cancer is provided, followed by a summary of the definitions, epidemiology and clinical presentation of head and neck, oral cavity cancer and oral potentially malignant disorders. Thereafter a description of relevant risk factors and preventive approaches is described. Of particular relevance is secondary prevention and the importance of detecting lesions at an early stage. Various types of screening are described, followed by a summary of the literature relating to factors associated with an examination of the oral cavity for oral cancer. This includes the potential techniques and methodologies that can be used and the perceptions of oral health professionals and patients around "screening"/examination of the mouth for oral cavity cancer. Finally, the summary of the literature will include identification of uncertainties and gaps in the literature and this will provide the rationale for the studies undertaken and presented in this thesis.

1.2 Non-communicable Diseases

In 2016, around 40.5 million deaths were caused by non-communicable diseases (NCDs) worldwide, accounting for 71% of all global deaths (Bennett et al., 2018). An estimated 80% of these NCD deaths were due to a combination of cardiovascular diseases, cancers, diabetes and chronic respiratory diseases. Approximately two thirds of the estimated NCD deaths occur in low- and middle-income countries. Genetic, physiological, behavioural and environmental factors are the main causes of NCDs (WHO, 2011; Balbus et al., 2013). The NCD Countdown 2030 collaboration (Bennett et al., 2018) advocates for policies that will reduce risk factors and determinants and calls for equitable access to high quality and effective preventive, diagnostic and treatment services for NCDs. Such policies are very relevant for the prevention, early detection/ screening and treatment of oral cavity cancer.

Among the NCDs, cancer remains the second leading cause of death around the world (WHO, 2018). In 2018, approximately 9.6 million deaths occurred at the global level due to cancer, accounting for about one in six deaths. Cancer is described as a "large group of diseases that are characterised by abnormal growth of cells (tumour) beyond the limits of their usual boundaries, often accompanied by invasion into adjoining parts of the body and spread to other organs" (WHO, 2018). Health professionals often refer to cancers based on their histological type such as squamous cell carcinoma, verrucous carcinoma or undifferentiated carcinoma. However, they and the general public also use cancer names based on their primary sites, such as lung, breast, colon, prostate, uterus, skin, and head and neck cancer (NIH, 2019).

1.3 Head and Neck Cancer

Head and neck cancer (HNC) sites include the oral cavity, pharynx, larynx, paranasal sinuses, nasal cavity and salivary glands (NIH, 2019). Most head and neck cancers develop in the squamous cells in the upper aerodigestive epithelium (Argiris et al., 2003; Rivera, 2015) and are known as squamous cell carcinomas. In 2018, head and neck cancer was described as the seventh most common cancer across the world, with just under 900,000 new cases and 450,000 deaths (Bray et al., 2018). Estimated HNC incidence rates vary widely around the world, from 26.3 per 100,000 persons in Melanesia to 2.2 per 100,000 persons in Western Africa (Hashim et al, 2019). This is likely due to differing rates of exposure to the main risk factors. Hashim and co-authors (2019) also report that the average age of HNC diagnosis is between 50 and 70 years and that the incidence rate is higher in males than females, with the ratio ranging from 2:1 to 4:1.

Very many cases of HNC are diagnosed at an advanced stage with consequent impact on survival rates and morbidity due to less effective treatment and more radical surgery to organs required for functions such as speech and swallowing (Hashim et al, 2019). In addition to surgery, radiotherapy and chemotherapy can impact outcome (Pauloski et al., 1998; Jehn et al., 2019), including quality of life (QoL) (Van der Waal et al., 2011; Wong and Wiesenfeld, 2018).There is, however, a high level of heterogeneity among head and neck sites in terms of epidemiology, natural history, treatment and prognosis (Chow, 2020). Consequently, it is important to focus on specific sites of interest when undertaking work aimed at gaining a better understanding of the disease from the perspective of burden, risk factors, diagnosis, treatment and preventive services. The term "oral cancer"

has often been used in the literature to describe a subgroup of HNCs, but this can be further divided into oral cavity and oropharyngeal groups, and the former grouping is the focus of this thesis.

1.4 Oral Cancer Definition

Within both the peer-reviewed literature and cancer registry reports, oral cancer has many definitions, with different terms used and variations in subsite inclusion (Conway et al., 2018). Attribution of specific subsites to either the oral cavity or the oropharynx can vary, and some subsites have been included in both. Consensus is important to allow study of factors such as epidemiological trends, aetiology and tumour behaviour.

The standard classification disease codes relevant to cancer sites are the World Health Organization's International Statistical Classification of Diseases and Related Health Problems 10th revision (ICD-10) and the International Classification of Diseases for Oncology (ICD-O). Recently, Conway and co-authors (2018) have reviewed the ICD-10 codes and recent major epidemiological studies and have suggested a "compromise" method for defining oral cavity and oropharyngeal cancers. This is based on anatomy and association with human papillomavirus (HPV). Using this method, the oral cavity has been defined as the sites: the inner lip (C00.3-C00.9), other and unspecified regions of the tongue (C02) (excluding lingual tonsil [C2.4]), gum (C03), floor of mouth (C04), palate (C05), and other unspecified parts of the mouth (C06). The oropharyngeal cancer sites have been defined as: the base of the tongue (C01), lingual tonsil (C2.4), tonsil (C09), oropharynx (C10), and pharynx unspecified including Waldeyer's ring / overlapping sites of oral cavity and pharynx (C14).

1.5 Oral Cavity Cancer

The US National Cancer Institute has used a slightly different definition of the oral cavity to that outlined above, namely, it has described it as including "the lips, the lining inside the cheeks and lips, the front two thirds of the tongue, the upper and lower gums, the floor of the mouth under the tongue, the bony roof of the mouth, and the small area behind the wisdom teeth" (NCI, 2020).

The oral cavity is lined by oral mucosa, which is mainly stratified squamous epithelium and a lamina propria of dense connective tissue (Syrjänen, 2003). The epithelium tends to

be keratinized in areas which are subject to continuous friction such as the hard palate (Bruch, 2017). In highly mobile areas, such as the soft palate and the floor of the mouth, the lamina propria is connected to the underlying structures via loose submucosal supporting tissue, whereas in the bony areas, such as the hard palate, the lamina propria is bound to the periosteum by a dense fibrous submucosa (Kumar, 2015).

Oral cavity cancer develops when cells undergo changes known as "mutations" (Rivera, 2015). It most commonly starts in epithelium cells, with almost 90% being oral squamous cell carcinoma in origin (El-Naggar et al, 2017). What causes cell mutation is still unclear, but there are number of risk factors that have been identified and may increase the risk of mouth cancer (West et al., 2006; Antunes et al., 2013; Winn et al., 2015). These will be explored further in Section 1.8.

1.5.1 Global Patterns of Oral Cavity Cancer

Oral cavity cancer (OCC) has been described as a public health problem which carries significant morbidity and mortality (McGurk, 2010). In 2018 it was estimated that cancers of the lip and oral cavity combined represented the 16th most common cancer globally, with approximately 355,000 new cases and over 177,000 deaths during that year (Bray et al., 2018). The site definition was based on the WHO Classification of head and neck tumours (El-Naggar et al, 2017) and extended from the lip to buccal mucosa, with inclusion of the tongue, mouth, floor of mouth and palate. It is recognised that incidence rates and deaths vary greatly across the world and it therefore important that there is an understanding of these regional patterns to enable the development of relevant preventive and treatment strategies.

An update of global patterns and trends of cancers of the lip, tongue and mouth has recently been published (Miranda-Filho and Bray, 2020). The information relating to incidence and death rates were extracted from IARC's GLOBOCAN database of national estimates, available at the Global Cancer Observatory. Overall, incidence and mortality rates were higher in males than females, with age-standardised incidence rates per 100,000 ranging by region from 0.5 to 21.2 in males and from 0.5 to 12.0 in females. In relation to both incidence and mortality, the countries with the highest rates included Papua New Guinea, Pakistan, India, Bangladesh and Afghanistan. The authors stated that cancers of the lip, tongue and mouth combined were the most common form of cancer in males in

both India and Pakistan, and the second most common in Papua New Guinea. They also examined temporal trends in the incidence of mouth cancer and reported most national registries, including some European countries, are showing a decreasing trend in males. In contrast, for females, a different pattern is being observed, with increasing rates seen in most populations, particularly in many European countries.

1.5.2 Patterns of Oral Cavity Cancer in Oman and Scotland

As this thesis relates to work conducted in the Sultanate of Oman (referred to as Oman) and in Scotland, it is relevant to describe the patterns of OCC in these two countries.

1.5.3 Patterns of Oral Cavity Cancer in Oman

A hospital-based registry, known as The Oman Cancer Registry, was established in 1985 and since 1996 this has functioned as a population-based cancer registry. A comprehensive report on 'Cancer Incidence in Oman' is published annually by the Department of Non-Communicable Disease, and the report for 2016 was published in 2019 (MOH, 2019).

The report provides data on incidence rates, based on the estimated mid-year population. The age standardised rates, adjusted to the world standard population, for all cancers among Omanis in 2016 were 67.4 per 100,000 for males and 79.3 per 100,000 for females.

The annual report does not refer to oral cavity cancer (OCC) as an entity but does, however, provide data for head and neck cancer. Additionally, age-adjusted incidence rates are presented for the ICD-10 codes relating to the individual sites of lip (C00), tongue (C01-02) and mouth (C03-06).

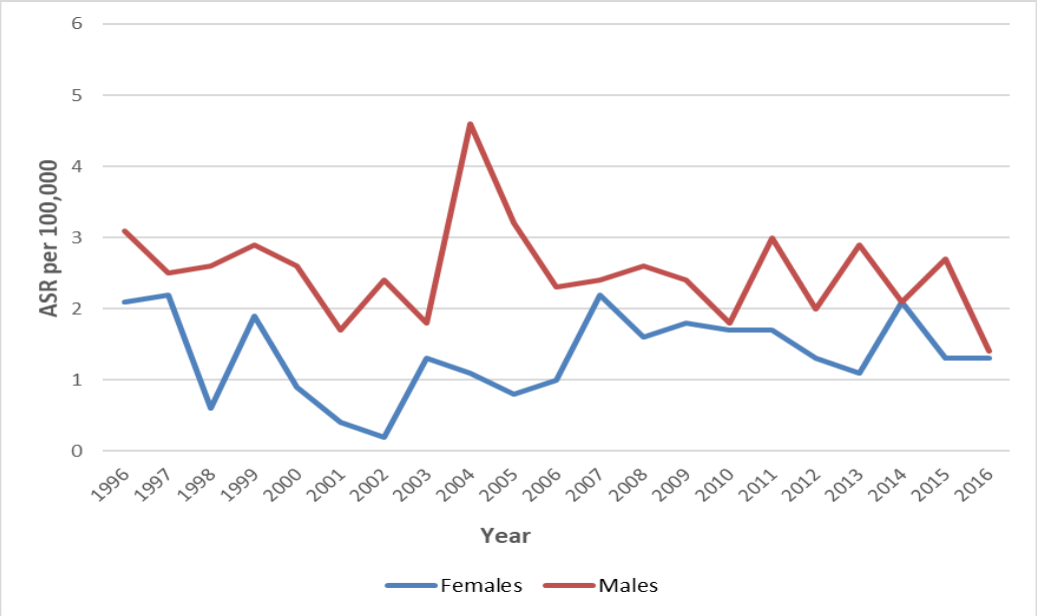
In the report for 2015 (MOH, 2018), HNC was listed as the 9th most common cancer in Oman. In the following year, it was not within the list of the 10 most common cancers. For this latter year, the age standardised incidence rate for head and neck cancer was 3.0 per 100,000 for males and 1.9 per 100,000 for females. The trends in head and neck cancer over the past 20 years show a fall from approximately 5.0 to 3.0 per 100,000 for males, while the age standardised incidence rate for females has remained stable at around 2.0 per 100,000.

The annual report also compares the age-standardized incidence rate (per 100,000) of HNC in Oman with selected other countries in the region, for the years 2008-2012. The

estimated value for females in Oman was similar to Bahrain and lower than other Gulf Cooperation Council (GCC) countries (e.g. Kuwait and Qatar), while the rate for Omani males was the lowest rate among other GCC countries (MOH, 2018).

The age standardised incidence rates presented in the 2016 annual report (MOH, 2019) for cancers of the lip, tongue and mouth have been combined for the purposes of this thesis to produce a rate for 'oral cavity cancer'. These rates (per 100,000) were 1.4 for males and 1.3 for females. The trends in incidence rate of oral cavity cancer in Oman for males and females from 1996 to 2016 are shown in Figure 1.1.

Figure 1.1 The trends in the age-standardised incidence rates per 100,000 of oral cavity cancer in Oman, 1996-2016



Source: Data from Ministry of Health - Oman

1.5.4 Patterns of Oral Cavity Cancer in Scotland

A recent article by Conway and co-authors (Conway et al., 2018) described the epidemiology of oral cavity cancer across the UK. Data from individual cancer registries in Scotland, England, Wales and Northern Ireland were re-analysed using the site definitions described in Section 1.3 to allow a standardised inclusion of codes and meaningful comparison of rates among countries. For Scotland, the age-standardised incidence rates (per 100,000 person-years) for OCC in 2016 were 10.0 for males and 5.6 for females. These rates were higher than in the other UK nations for both genders. For

males in 2016, the incidence rate for OCC in Scotland was similar to that for oropharyngeal cancer (10.0 and 9.7 per 100,000, respectively), while for females the rate for oropharyngeal cancer was lower at 2.7 per 100,000. The burden of both oral cavity cancer and oropharyngeal cancer is higher for those from socio-economically disadvantaged areas.

According to Conway, Purkayastha and Chestnutt, (2018) trends in the incidence rates for oral cavity cancer in Scotland (males and females combined) remained relatively stable between 2000 and 2016. They were consistently higher than those observed in the other UK countries over the time period, although a steady rise in rates was seen in both England and Wales. The trends for oral cavity cancer in Scotland differ to those seen for oropharyngeal cancer. Over the same period a rapid rise in the incidence of oropharyngeal cancer has been seen both in Scotland and the other UK nations. Analysis of data from Scotland and England has projected that the incidence rates of oropharyngeal cancer will overtake those of oral cavity cancer over the next decade.

Ingarfield and co-workers (Ingarfield et al., 2019) have investigated the survival of head and neck cancer patients in Scotland from an inequalities perspective. Based on a cohort of head and neck cancer patients, unadjusted models showed a clear gradient in survival across deprivation groups at 1-, 5- and 12-years. Following adjustment for patient, tumour and treatment factors (for example: age, sex, smoking and alcohol behaviour, site and stage of the tumour) the inequality was no longer present, suggesting that many factors play a role in the inequality of survival of patients with head and neck cancer.

1.5.5 Clinical Presentation of Oral Cavity Cancer

Oral cavity (or mouth) cancer can present in a number of different ways (Lewis, 2018) and a major problem is that many cases present at an advanced stage with consequential impacts on survival rates and quality of life. Lewis (2018) has pointed out that tumours within the oral cavity grow at different rates and that the size of the lesion and presence or absence of regional metastatic spread at the time of diagnosis is more important than how long it has been present. However, it is acknowledged that an advanced stage of the tumour is very often associated with late diagnostic detection of the disease (Hashim et al, 2019).

A classical presentation is described as a single deep ulcer with rolled margins on the lateral border of the tongue. However, it can also present as a swelling, as erythema or as

speckled red and white patches. The site, size, and clinical and histological appearance of OCC all influence survival rates (Lewis, 2018).

Oral cavity cancer does not, however, have mutually exclusive signs and symptoms (McGurk and Scott, 2010). Thus, many lesions of the oral cavity, for example some white patches such as frictional keratosis, will not have any malignant potential, while others may have mucosal abnormality and be potentially malignant. This has important implications for the examination of the mouth for oral cavity cancers in primary dental care and for the appropriate referral of patients with "suspicious lesions" to secondary care (McGurk and Scott, 2010). This will be discussed in greater depth later in the thesis.

1.6 Staging of Oral Cavity Cancer

Cancer Research UK (NCI, 2015) indicates that mouth cancer can be staged using the number staging system or the TNM classification. As indicated in Table 1.1 below, the numbering system usually divides mouth cancer into four main stages, with stage 1 representing an early cancer and stage 4 an advanced cancer. Additionally, stage 0 is sometimes used to describe cancer at a very early stage, described variably as carcinoma in situ or pre-cancer.

Table 1.1 Mouth cancer staging

Stages	Descriptions
Stage 0	Carcinoma in situ or pre-cancer. There are abnormal cells but they are contained within the lining of the mouth with no spread.
Stage 1	The earliest stage of invasive cancer. The cancer is 2 cm or smaller and no more than 5 mm deep. There is no spread to nearby tissues, lymph nodes or other organs. In the TNM staging system this is T1, N0, M0.
Stage 2	The cancer is larger than in stage 1 (can be up to 4 cm in size and 10 mm in depth) but has not spread to nearby lymph nodes or other organs. In the TNM staging system this is T2, N0, M0.
Stage 3	The cancer is larger than 4 cm or 10 mm deep with no spread to lymph nodes or other parts of the body: T3, N0, M0; or the cancer is any size but one lymph node on the same side has cancer cells, with the lymph node being no more than 3 cm across: T1, 2 or 3, N1, M0.
Stage 4	The cancer is advanced. This is further divided into three stages: 4a, 4b and 4c. In stage 4c, the cancer has spread to other parts of the body such as the lungs or bones: any T, any N, M1.

The stage of the cancer influences both treatment options and outcomes. Detection of oral cavity cancer in the early stage, when the lesion is less than 2 cm with no local spread or

metastasis (stage 1) is associated with a high 5-year survival rate of around 85%, whereas for a stage 4 tumour, the 5-year survival rate is only around 10% (Lewis, 2018).

It is now understood that oral cavity cancers arise from non-invasive lesions of the stratified squamous epithelium and that histologically these lesions can range from normal mucosa to high grade dysplasia / carcinoma in situ, representing a model of neoplastic progression (Ray, 2017). These conditions are known as Oral Potentially Malignant Disorders (OPMD) (Lewis, 2018), with the advanced end of the spectrum corresponding to Stage 0 described above.

1.7 Oral Potentially Malignant Disorders (OPMD)

Oral potentially malignant disorders (OPMDs) consist of a diverse group of conditions that may precede the development of oral squamous cell carcinoma. In 2020, a comprehensive review of the clinical and management aspects of OPMDs was published (Warnakulasuriya, 2020). This described the changing terminologies used over the past decades, conditions and definitions within this group, prevalence and risk factors associated with the disorders, as well as clinical appearance, malignant transformation rates and management options.

Ray (2017) has also reported on the historical evolution of terminologies associated with oral disorders and related cancers. Until 2007, the terms commonly used to describe oral potentially malignant disorders were “precancer” or “premalignant” lesions or conditions. However, following an expert group meeting of the WHO Collaborating Centre for Oral Cancer, these terms were replaced with the OPMD terminology. This combined the terms “lesion” and “condition” into that of “disorder” and used the term “potentially malignant” in recognition of the fact that not all disorders would progress to malignancy over time (Warnakulasuriya, 2020).

Many conditions are recognised as OPMDs, meaning that a patient with any of these disorders has an increased risk of developing mouth cancer compared to those with a healthy oral mucosa. The most common and / or important OPMDs include: leukoplakia; erythroplakia; erythroleukoplakia; proliferative verrucous leukoplakia; oral submucous fibrosis and oral lichen planus. Definitions exist for each of these disorders and it is important that these are used both in clinical practice and for epidemiological purposes (Warnakulasuriya, 2020). For example, misclassification of oral leukoplakia, to include

white patches which carry no increased risk of oral cancer, can lead to a diverse range of prevalence figures being reported for this condition.

Ray (2017) has noted that it is difficult to get accurate data on the global prevalence of OPMDs as information is sparse. However, according to a recent systematic review (Mello et al., 2018), epidemiological surveys have estimated a global prevalence of OPMDs of around 4.5%, with variation among different populations. The prevalence is generally higher among Asians and males and the average age of patients with OPMDs is said to be between 50 and 69 years.

Warnakulasuriya (2020) reports that there is no consistent pattern regarding the natural history of OPMDs and that it is difficult to predict which lesions will progress onto cancer. A systematic review of observational studies related to oral leukoplakia showed a very wide range of malignant transformation rates (0.1% to 34.0%) (Warnakulasuriya and Ariyawardana, 2016). The OPMDs at high risk of malignant transformation include erythroplakia, eyrthroleukoplakia, proliferative verrucous leukoplakia and oral submucous fibrosis, while Warnakulasuriya (2020) has stated that the risks are lower in homogeneous leukoplakia and in oral lichen planus.

The major risk factors for the most common OPMDs are tobacco (both smoked and smokeless), high alcohol consumption and chewing betel quid containing areca nut (Warnakulasuriya, 2020).

Following diagnosis of an OPMD, patient management involves assessing risk, providing advice on risk factors, selecting an appropriate intervention and providing follow-up. Assessing risk is based both on individual risk factors and on clinico-pathological findings. These factors include age, ability to moderate lifestyle risk factors, presence of red areas in white and red patches and the grade of dysplasia identified pathologically (Warnakulasuriya, 2020).

As a result of evidence from a systematic review (Mehanna et al., 2009) suggesting that excision of lesions may reduce the risk of transformation, it is recommended that high risk lesions should be excised. However, due to the potential presence of field change within the oral mucosa, excision of a lesion may have limited effectiveness (Thomson, 2015; Lingen et al., 2017).

In summary, OPMDs are important risk factors for the development of oral cancer. Important points to note include: the use of agreed terminology; accurate diagnosis;

primary and secondary prevention relating to the main modifiable risk factors; excision of lesions where appropriate; and regular follow-up of patients at intervals determined by an individual risk assessment.

1.8 Risk Factors of Oral Cavity Cancer

Due to the relatively low incidence of OCC and the lag time between exposure to risk factors and cancer diagnosis, investigations of risk factors for OCC are usually undertaken via case-control studies (Conway et al., 2018).

The International Head and Neck Cancer Epidemiology (INHANCE) consortium is a collaboration of international researchers and research groups with large case-control studies which investigates the risk factors for head and neck cancer overall, and for the specific subsites including oral cavity and oropharyngeal cancer. The consortium undertakes pooled analysis of individual-level data from different studies on a large scale, thus enabling research questions relating to aetiology to be addressed in a way that would not be possible within individual studies (Winn et al., 2015). For example, the large volume of data allows precise estimates of risk to be calculated and the influence of confounding factors to be studied. The focus is on behavioural, social, environmental and genetic risk factors and the interactions among them (Winn et al., 2015). In 2018, it was reported that the consortium had pooled data from 35 studies across the world (including USA, Europe, Latin America, Brazil and Asia), with data on over 25,000 patients with head and neck cancer and over 37,000 controls (Conway et al., 2018).

A comprehensive review of the findings of the consortium was published by Winn and co-authors (2015). This aimed to provide a better understanding of the causes and mechanisms associated with HNC. The review acknowledged the lack of study data from areas of the world with very high rates of head and neck cancer, i.e. South-East Asia, and while INHANCE data are analysed at the subsite level, including oral cavity cancer, most of the findings presented within the review of the consortium's work were at the higher level of head and neck cancer. A review of risk factors specifically for oral cavity cancer (Radoï and Luce, 2013) has highlighted the problems of comparing findings from different studies due to the lack of uniformity in defining oral cavity cancer in terms of case definitions and sites included.

Detailed below is a brief review of the literature relating to the risk factors for head and neck and oral cavity cancer.

1.8.1 Smoked and Smokeless Tobacco

Findings from case-control studies have shown that tobacco smoking is a major risk factor for head and neck cancer (Radoï and Luce, 2013; Winn et al., 2015). Hashibe and co-workers *(*2007) estimated the effects of cigarette smoking among those who had never drunk alcohol and found the former behaviour to be associated with an over two-fold increased risk of head and neck cancer. Furthermore, the risks increased with frequency, duration and pack-years of cigarette smoking. The INHANCE consortium further studied the effect of total exposure to smoking (Lubin et al., 2009) and found that above 15 cigarettes per day, smoking fewer cigarettes per day, over a longer period of time was worse than smoking a higher number of cigarettes over a shorter period. An INHANCE study has also shown that within one to four years of quitting smoking, benefits can be seen in relation to reducing the risks of head and neck cancer (Marron et al., 2010).

Interestingly, the review by Radoi and Luce (2013) reports that several case-control studies have shown that the oral cavity seems to be the anatomical site within the upper aerodigestive tract which is least sensitive to the effects of smoked tobacco, with the most affected site being the larynx. They further report that this finding has been confirmed in large pooled analysis from INHANCE. In such analysis, they report the risk of OCC was 1.4-1.7 times higher in smokers than in non-smokers among never drinkers. As shown for head and neck cancer, their review also reported an increasing risk of OCC with increased frequency, duration and lifetime cumulative smoking history (Radoi and Luce, 2013).

Smokeless tobacco, used as powdered snuff or as tobacco chewing, has also been shown to have an increased risk association for oral cancer (Wyss et al., 2016), with an almost two-fold risk, even among those who have never smoked.

1.8.2 Alcohol Drinking

Hashibe and co-authors (2007), from an analysis of INHANCE data, estimated that alcohol drinking among those who had never used tobacco was linked to a two-fold increased risk of head and neck cancer, but only among heavier drinkers (three or more drinks per day). In a study of the pattern of alcohol consumption, INHANCE investigators found that there

was greater head and neck cancer risk from a higher intake over a shorter period of time compared with a lower intake over a longer period (Lubin et al., 2009).

The review of risk factors for oral cavity cancer (Radoi and Luce, 2013) reported that the risk seemed to increase with daily quantity, duration of consumption and lifetime accumulation. However, they pointed out that the pooled analysis of INHANCE data by Hashibe et al (2007), referred to above, found that the increase in risk of OCC in non-smokers by frequency and duration of alcohol consumption was low and statistically non-significant. This pooled analysis also showed that the risk seemed to be lower among heavy drinkers (five or more drinks per day) for the oral cavity (OR 1.2, 95% CI 0.6-2.6) than for the pharynx (OR 5.5, 95% CI 2.3-13.4).

1.8.3 Joint Effect of Tobacco and Alcohol Consumption

A number of studies have investigated the combined role of tobacco and alcohol consumption in oral cavity cancers and found the joint effect to be multiplicative or greater than multiplicative in most cases (Radoï and Luce, 2013). A pooled analysis of INHANCE data (Hashibe et al., 2009) found that compared to non-smokers and non-drinkers, those who smoke and drink have their risk of OCC multiplied by 4.8 (95% CI 2.6-8.8).

1.8.4 Betel Quid

Betel quid is used commonly in South Asia, Southeast Asia and the Pacific Islands and also by those of South Asian origin around the world, with a reported prevalence of betel quid chewing in the Solomon Islands of over 75% (Tovosia et al., 2007). In the regions mentioned above, a high proportion of oral cavity cancers can be attributed to this habit (Hashim et al., 2019). Betel quid consists of the areca nut and often slaked lime wrapped in the leaf or other part of the *Piper betle* plant. Other ingredients can include tobacco, spices and herbs.

A systematic review has reported that betel quid without tobacco had an almost three-fold increased risk association with oral cancer (Gupta and Johnson, 2014). Additionally, Radoï and Luce (2013) reported that a review of 11 case-control studies suggested that the odds ratios for betel chewing were 1.5-3 times higher than those for tobacco smoking and 2-11 times higher than for alcohol consumption. They also reported that chewing betel-tobacco

seemed to have around a two-fold higher odds ratio for oral cavity cancer than chewing betel alone.

1.8.5 Diet

A number of INHANCE studies have investigated the effect of diet on the risk of head and neck cancer. The analyses were based on dietary habit data collected via food frequency questionnaires. A pooled analysis (Bosetti et al., 2013) of studies showed that a dietary pattern based on foods high in antioxidant vitamins and fibre, such as fruits and vegetables, was associated with reducing by half the risk of head and neck cancer. A later study by Edefonti and co-authors (2015) showed a similar odds ratio for oral cavity/pharynx cancer when comparing the highest and lowest quintile of vitamin C intake. Winn et al (2015) have stated that these findings are similar to those of other large case-control studies which have also shown a protective effect of fruit and vegetables.

A recent paper from the INHANCE consortium (Bravi et al., 2020) has presented an update on finding from the group. In addition to confirming the above findings, they have also found an inverse association between drinking caffeinated coffee and head and neck cancer risk, and this was also found for the anatomical sub-site of the oral cavity.

Lubin and co-authors *(*2011) have investigated body mass index (BMI) and the risk of head and neck cancer. They found that compared to those of normal BMI, those with a low BMI had higher odds ratios for the disease, and furthermore that lower BMI levels also increased smoking and drinking-related risks of both oral cavity and pharyngeal cancers.

1.8.6 Oral Health

Conway and co-authors (2018) have reported that analysis of the INHANCE dataset has shown that, after adjusting for smoking and alcohol consumption, the positive oral health behaviours of daily toothbrushing and regular dental attendance may modestly reduce the risk of oral cavity cancer. Fewer missing teeth showed a similar finding. The review by Radoi and Luce (2013) indicated that case-control studies have found that decayed, broken and filled teeth were not associated with increased risk. While no increased risk is associated with the wearing of a removal denture *per se*, some studies have shown an increased risk, particularly on the tongue, from denture-associated sores associated with ill-fitting appliances (Radoï and Luce, 2013).

The risk associated with the use of mouthwashes, many of which contain alcohol, is uncertain. A pooled analysis by Boffetta and co-authors (2016) found a slightly elevated risk of oral cavity and oropharyngeal cancer after prolonged use (greater than 35 years) and use more than once per day. However, there were difficulties associated with recall bias and the ability to completely disentangle the confounding factors of smoking and alcohol consumption from this analysis. The authors therefore suggested that further research was required in this area.

1.8.7 Socioeconomic Status

The large number of case-control studies within the INHANCE consortium has enabled more precise measurement of the effects of education and income on head and neck cancer when adjusting for or ruling out the effects of tobacco smoking and consumption of alcohol. An analysis (Conway et al., 2015), involving 31 case-control studies, observed an over two-fold increased risk for both low education and income status that could not be accounted for by smoking, alcohol and dietary habits. Furthermore, the odds ratios were approximately 1.6 among those who neither smoked nor consumed alcohol. The authors therefore suggest that low education and income are risk factors for head and neck cancer, independent of the major risk factors of tobacco smoking and alcohol (Conway et al., 2015).

1.8.8 Marijuana

Marijuana smoke contains carcinogens at levels that can be higher than in tobacco smoke. This has raised concerns that marijuana smoke might be a risk factor for cancer (Hashibe et al., 2005). However, evidence for an association between marijuana and oral cancer is limited and difficult, partly due to the fact that many users of marijuana are also tobacco smokers and consumers of alcohol, leading to the likelihood of some residual confounding in analysis. A pooled analysis of INHANCE data did not find an increased risk of oral cavity cancer associated with marijuana use, and this included frequency per day and cumulative consumption over time (Berthiller et al., 2009).

1.8.9 Human Papilloma Virus (HPV)

HPV is the most common sexually transmitted virus and infection is associated with oropharyngeal cancer rather than oral cavity cancer risk (Smith et al., 2004). HPV 16 and HPV 18 subtypes are the main high-risk oncogenic types (Gillson et al., 2015). This review by Gillson and co-workers found that oral HPV is more prevalent amongst men than women. They also identified factors associated with carriage of oral HPV which included tobacco and alcohol use, oral sex, multiple sexual partners, same sex partners and earlier sexual debut. In theory, HPV associated oropharyngeal cancers can be prevented by behaviour modifications, safer sex practice and vaccinations (Gillison et al., 2012). An international, multi-centre case-control study reported that the proportion of HPV positive oropharyngeal cases were 60% in the USA and 31% in Europe (Anantharaman et al., 2017). It is assumed that the HPV attributional proportion in Europe is likely to be rising to closer to that of the USA with the rapid increasing number of cases of oropharyngeal cancer seen in recent years in Europe (Conway et al., 2018). The aetiological fraction for oral cavity cancer has been estimated to much lower, perhaps as low as 3% (Gillison et al., 2015).

1.8.10 Genetics

Genetics have been implicated as a risk factor for oral cancer (Winn et al., 2015). Certain genetic loci, including several related to nicotine and alcohol metabolism and DNA repair pathways have been found to be associated with head and neck cancer risks. This, therefore, demonstrates the potential for “genetic-environmental risk interactions” (Winn et al., 2015). INHANCE studies have also identified a moderately strong hereditary risk, with a suggested increased risk associated with having a first degree relative with head and neck cancer (Negri et al., 2009).

1.8.11 Summary of Risk Factors

In summary, pooled analysis of large case-control studies has enabled investigation of risk factors for HNC and OCC, with calculation of precise estimates of risk and appropriate adjustments for confounding factors. Identification of risk factors are essential for the

development of appropriate preventive strategies at both individual and population levels and to enable the assessment of individual risk within a primary health care setting.

1.9 Prevention of Oral Cavity Cancer

The practices of maintaining health and well-being are not new and, since ancient times, wisdom has decreed that "prevention is better than cure." As indicated in earlier sections, non-communicable diseases, including cancer, are a major burden both to individuals and to health care systems (Levine et al., 2019).

The WHO (2020) has stated that, in the long-term, prevention offers the most cost-effective strategy for the control of cancer. It calls for national policies to be developed and implemented to reduce exposure to cancer risk factors, raise awareness of the disease and provide information to support the adoption of healthy lifestyles. The organisation estimates that between 30-50% of all cancer cases are preventable and that, at the global level, tobacco is the single greatest avoidable risk factor for cancer deaths.

Implementing appropriate preventive health care strategies can have a profound effect on the quality of life of individual people and populations and can also have a major impact on health care provision and spending (Levine et al., 2019). Such preventive strategies can be described as primary, secondary or tertiary in nature (Reichart, 2001).

Primary prevention refers to activities or measures that are directed towards reducing the risk of exposure to a risk factor (for example smoking and alcohol consumption) or a health determinant at either the individual or population level (Reichart, 2001). It is described as intervening before health effects occur (Wallace and Chen, 2006). Secondary prevention involves detecting and treating disease at an early stage. Examples include screening processes to identify unrecognised disease in an apparently healthy, asymptomatic population (WHO, 2020a) through measures such as regular blood pressure checks and mammography. Secondary preventive measures are said to focus on the sub-clinical and the early clinical stages of a disease (D'souza and Addepalli, 2018). These measures "enable early detection and prompt effective intervention to correct departures from a state of health" (D'souza and Addepalli, 2018). Tertiary prevention is managing diseases post-diagnosis to slow disease progression. The main purpose of the third level of prevention is to reduce or eliminate long-term impairments and disabilities, minimize

suffering, optimise function, assist in adjusting to limitations in health and function resulting from the event, and sometimes extend survival (Hoey et al., 2019).

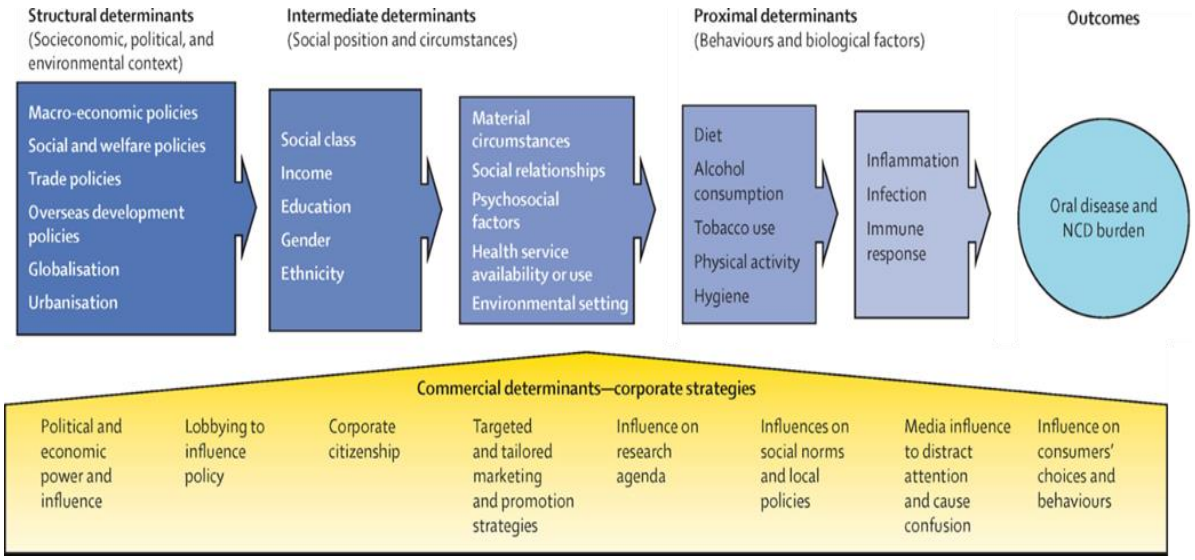
Low OCC survival rates are associated with late diagnosis and risk-associated behaviours therefore both primary prevention, to reduce incidence, and secondary prevention, to improve early detection, are key approaches for reducing the burden associated with this disease. The work of this thesis focusses primarily on the examination of the oral cavity for signs of potentially malignant or early malignant disease. This is an example of secondary prevention and will be discussed further. A brief review of factors pertinent to the primary prevention of OCC will also be provided, but tertiary prevention is out with the scope of this work.

1.9.1 Primary Prevention of Oral Cavity Cancer

1.9.1.1 Structural, Intermediate and Proximal Approaches

As indicated in earlier sections, smoking and excessive alcohol consumption are two of the major risk factors for OCC. These behaviours can be described as proximal factors or "causes" of the disease. However, it is now recognised that such behaviours are influenced by the environments and circumstances in which people live. These are described as intermediate determinants and include material circumstances; levels of social interaction and community cohesion; access to amenities and services; and psychosocial factors such as stress. These circumstances are, in turn, affected by structural determinants such as economic, social and welfare policies at national level (Peres *et al.*, 2019). These structural and environmental factors are therefore described as the "causes of the causes" (Figure 1.2). The structural, intermediate and proximal levels can also be described as upstream, midstream and downstream determinants, respectively. To add to the complexity, large, multi-national corporations, such as the tobacco and alcohol industries, also have a major influence on behaviours and they too operate at these three levels. For example, through lobbying of policymakers, marketing at the community-based intermediate level, and by influencing the social norms of individuals. These concepts have recently been described Peres and co-authors (2019).

Figure 1.2 Social and commercial determinants for oral disease



Source: Peres *et al* (2019)

For the reasons outlined above, it is now accepted that solely providing risk factor-related information and advice to individuals will have limited impact on changing behaviour and thus preventing diseases such as OCC. In addition to individual-level (proximal) behavioural approaches (for example primary care-based one-to-one counselling, health education and pharmacological treatments associated with smoking and / or alcohol consumption), for optimal effects, public health interventions for disease prevention should also include intermediate and structural approaches. The different policy levels advocated to prevent disease, promote health and reduce health inequalities from the Dahlgren and Whitehead (1991) model are:

1. Strengthening individuals (downstream)
2. Strengthening communities
3. Improving infrastructure and access to services
4. Making structural changes to economic, cultural and environmental conditions (upstream)

A successful use of this approach has been seen in relation to the tobacco control agenda. The WHO Framework Convention on Tobacco Control (FCTC) (WHO, 2004) has facilitated a global, coordinated action to reduce tobacco consumption, lower smoking rates among children, and counteract the tobacco industry's lobbying, promotional and advertising activity. By 2019, 181 countries had ratified or acceded to the treaty (Hoffman

et al., 2019). Provision within the treaty requires that parties implement measures such as: limiting the interaction between lawmakers and the tobacco industry; taxation and other measures to reduce demand; protecting people from the effects of passive smoking; health warnings on packaging; banning tobacco advertising; raising public awareness of the harmful effects of smoking; offering help to people to end their addictions to tobacco; and banning the sale of tobacco products to minors. The former WHO Director-General Margaret Chan has said that "without question, the WHO Framework Convention on Tobacco Control is the most powerful tool we have, as an international community, to reduce the global disease burden" (Chan, 2008).

1.9.1.2 Common Risk Factor Approach

OCC and other oral diseases share many of the same modifiable risk factors as other NCDs (Glick et al., 2012). These include tobacco use, high alcohol consumption, unhealthy diets and socio-economic determinants. Therefore, adopting a shared and common risk factor approach to prevention is considered rational (Sheiham and Watt, 2000), and the integration of oral health into NCD prevention and control strategies is advocated. The adoption of the common risk factor approach by health professionals can contribute to health improvement across many systems, including oral health, and oral health professionals can contribute not only to oral health but also to general health.

In 2011, the United Nations (UN) convened the first high-level meeting on the prevention and control of NCDs. The outcome of the meeting was a UN political declaration which included for the first time reference to oral diseases within the context of NCDs (Nation, 2011). Article 19 of the Declaration stated that "UN member states recognize that renal, oral and eye diseases pose a major health burden for many countries and that these diseases share common risk factors and can benefit from common responses to non-communicable diseases" (Mensah and Mayosi, 2013). More recently, the WHO produced a global action plan for the prevention and control of NCDs (WHO, 2015). This plan, for the period 2013-2020, provided a road map and policy options for nations and organisations to adopt to help address the burden of NCDs. It emphasised the need for multisectoral action at all levels, and the four shared behavioural risk factors highlighted were tobacco use, unhealthy diet, physical inactivity and the harmful use of alcohol. The action plan mentioned oral diseases, including oral cancer, and in addition to commenting on the shared health benefits from preventive approaches relevant to oral cancer, it also included as an objective

"oral cancer screening among high risk groups (e.g. tobacco users, betel nut chewers) linked with timely treatment" (WHO, 2015).

1.9.2 Secondary Prevention of Oral Cavity Cancer

The oral cancer-related objective mentioned above is an example of secondary prevention and is reminder that while concerted approaches and efforts are being made to prevent NCDs, including OCC, the diseases remain within populations, with associated high burdens on individuals and society. Recent advances in the treatment of head and neck cancer have resulted in some improvements in outcomes, however, cancer in this anatomical region is still associated with high morbidity including pain, disfigurement, dysfunction, psychosocial distress, as well as death (Van der Waal et al., 2011; Wong and Wiesenfeld, 2018; Chow, 2020). These outcomes are related to the often-late presentation of the disease and, as described earlier, the poorer survival rates associated with more advanced stages of the cancer. It is therefore important that lesions are detected and treated at an early stage to improve patient outcomes and reduce service costs.

1.10 Early Detection/ Screening

Brocklehurst and Speight (2018) have stated that the oral cavity is easy to examine and oral lesions relatively easy to detect. There has therefore been interest and debate for many years on screening for mouth cancer.

Screening aims to detect disease early and has a number of definitions. Some, such as that of the World Health Organisation (WHO, 2020b), relate to screening programmes: "screening is defined as the presumptive identification of unrecognized disease in an apparently healthy, asymptomatic population by means of tests, examinations or other procedures that can be applied rapidly and easily to the target population." Furthermore, the UK National Screening Committee (Public Health England, 2019) defines screening as "the process of identifying healthy people who may have an increased chance of a disease or condition. The screening provider then offers information, further tests and treatment. This is to reduce associated problems or complications. Screening should always be a personal choice."

The recent Report of the Independent Review of Adult Screening Programmes in England states that the term 'screening' is widely used in the health care setting and can take many

different forms (NHS England, 2019). These range from national population screening programmes (such as breast and bowel cancer screening) to screening that occurs as part of routine health care (such as general medical practice screening for high blood pressure during an appointment for another problem). This report (NHS England, 2019) describes a hierarchy of screening, with the main types being as follows:

- National population programmes which target large groups of the population to screen for early signs of cancer or disease. For example, cervical, breast and bowel cancer screening.
- Targeted or risk stratified screening which seeks to target screening at people who are at higher risk of a cancer or disease. For example, women with a family history of breast cancer.
- Opportunistic screening - recommended for certain groups but which does not involve them being actively invited for screening. For example, the National Chlamydia Screening Programme which aims to regularly test young sexually active individuals for chlamydia.
- Screening delivered as part of routine health care. This is described as a type of screening which is not part of a national screening programme and occurs during the provision of health care. The report includes "a dentist screening for oral cancer during a routine check-up" as an example of such an activity.

1.10.1 Screening Approaches for Oral Cavity Cancer

Several approaches have been considered for oral cavity cancer screening programmes and these include targeting high risk individuals and opportunistic screening within primary health care. The main test is a visual inspection, but genetic-based tests and HPV testing have also been considered (Hashim et al., 2019). However, these authors have identified three major barriers to the implementation of large-scale screening for OCC. These are: 1] the lack of evidence that such an approach is effective in substantially reducing mortality; 2] a lack of consensus on who within the population should be screened; and 3] a lack of a risk-based screening protocol for OCC that can be easily applied.

A Cochrane systematic review of oral cancer screening programmes identified only one study worldwide which had been properly conducted and which evaluated the clinical efficacy of mouth cancer screening (Brocklehurst et al., 2013). This large cluster-randomised controlled trial was carried out in Kerala, South India over a 15 year period and involved four rounds of screening using a conventional oral examination (Sankaranarayanan et al., 2013). Although no significant difference was found in oral cancer mortality between the intervention and control groups, at the end of the trial a

significant (24%) reduction in mortality was seen for high risk groups (those who smoked and/or consumed alcohol) in the screened compared to the control group. While the Cochrane review acknowledged the significant findings of the trial, they identified a high risk of bias associated with the study and concluded that further studies were needed to recommend population screening programmes.

Many countries set specific criteria for determining whether national screening programmes are appropriate, and these usually cover the following areas: the condition, the test, the intervention, the screening programme and the implementation criteria. The UK National Screening Committee (NSC, 2003) assesses potential new screening programmes against 20 criteria within these five topic areas. Brocklehurst and Speight (2018) have explored the potential strengths and limitations of a national screening programme for oral cancer in the UK and have shown that many of the screening criteria outlined above have either not been met or not been evaluated in relation to this disease. A computer modelling simulation of the costs of screening for oral cancer in different health care settings was carried out by Speight and co-worker (2006). Their results suggested that in the UK, oral cancer screening could be cost-effective if it were targeted to high risk individuals and carried out opportunistically by general medical practitioners and / or general dental practitioners. Thus, Brocklehurst and Speight (2018) state that although there is some evidence to suggest that the screening of high risk groups may be effective and cost-effective, they conclude that there is insufficient evidence for the setting up of national programmes. Additionally, they make the point that similar conclusions have been reached by Government bodies around the world and therefore none have recommended oral cancer screening as part of a national programme.

Issues with a screening programme relate to the prevalence of the disease and to the fact that studies investigating “screening” for oral cancer have included OPMDs within the criteria of a positive test, although it is known that the overall malignant transformation rate is low. Brocklehurst and Speight (2018) also question whether an opportunistic screening programme for oral cancer would be effective in a dental practice setting, as many of those at highest risk of oral cancer are unlikely to be regular dental attenders. Interestingly, the American Cancer Society has recommended that oral cancer screening is carried out as part of a general cancer check-up by physicians. Furthermore, a strategy document associated with the US Department of Health and Human Services has set goals for 2020 to increase the number of adults receiving an annual examination for mouth

cancer and the proportion of oral cancers diagnosed at an early stage (Hashim et al., 2019). However, these authors state that less than 20% of adults in the US, over the age of 40 years, report having had an examination for oral cancer during their lifetime.

Thus, in countries with relatively low incident rates and primary dental care systems in place, current evidence supports the examination of the mouth for cancer as fitting into the category of "screening delivered as part of routine health care" (Public Health England, 2019) rather than a national screening programme, and efforts are being made to increase compliance and implementation via regulations, recommendations and guidelines (Hashim et al., 2019). However, these authors caution that the evidence on which such recommendations have been made are reported to be low.

Although the hierarchy mentioned above divides "opportunistic screening" and "screening delivered as part of routine health care" into two separate entities, within the oral cancer literature, the two terms are often used interchangeably when referring to an examination of the mouth for OCC when attending a routine dental appointment.

1.11 Examination of the Mouth for Oral Cavity Cancer as Part of a Routine Dental Appointment

Dental professionals working in primary dental care have the opportunity to carry out an examination for oral cavity cancer and OPMDs when patients attend as part of routine health care.

Many guidance documents and online sites (NIH, 2013; CRUK, 2015) provide advice on how to conduct an intra- and extra-oral examination of the mouth for signs of mouth cancer or potentially malignant lesions. There is some variation in the content and extent of the methodology recommended but, overall, this tends to consist of a visual examination of the sites within the oral cavity and facial region, and palpation of the regional neck nodes. This is known as a 'conventional oral examination' (COE). This two-step method of screening has been described by the US National Institute of Health (NIH, 2013) guide for oral health care professionals (2013) as follows: "The examination is conducted with the patient seated upright. All prostheses are removed. The extraoral and perioral tissues are checked first, starting with an inspection of the face, head and neck region. Any changes in facial symmetry or on the skin such as colour, fissuring or growth need to be documented. The regional lymph nodes are then palpated bilaterally for any kind of enlargements. A

recommended sequence should be followed including: preauricular, submandibular, anterior cervical, posterior auricular and posterior cervical regions. In step two, the oral health care professionals should follow a seven-step systematic assessment of the lips, labial mucosa and sulcus, commissures, buccal mucosa, gingiva, tongue, floor of the mouth and the palate".

Recommendations relating to a COE are often communicated through clinical guidelines for dental health care professionals working in primary care and have been developed by a wide range of different health and professional organisations and agencies in many parts of the world (e.g. American Cancer Society ACS, 2003; SIGN, 2006; US Preventive Service Task Force USPSTF, 2014). Additionally, some regulatory bodies have made it a requirement that a COE is carried out, for example the General Dental Council in the UK (GDC, 2012). Furthermore, the GDC recommends that dental health professionals should keep their skill up to date by undertaking continuing professional development in the area of "oral cancer – early detection" (GDC, 2019). However, in other parts of the world, including Oman, no national guidance or advice from regulatory bodies exist.

A review by Walsh and co-authors (2013) has reported that a COE is better at classifying the absence of OCC or OPMDs in disease-free individuals than in classifying the presence of these conditions in those affected by the diseases. This is due to the fact that carrying out a COE may not be sufficient to distinguish an innocuous lesion from one which is malignant or potentially malignant (Lingen et al., 2017). For this reason, McGurk and Scott (2010) have argued that while an examination for oral cancer on all patients attending primary dental care may seem laudable, clinical guidelines can be poor at helping practitioners to discriminate between OPMDs and other diseases of the soft tissue. Thus, detecting and referring patients with all such lesions to secondary care has the potential to swamp the health care system. They further argue that the policy of carrying out a COE on all patients attending dental primary care has had limited effectiveness to-date, with limited change in the proportion of patients diagnosed with stage 1 and stage 4 tumours over many decades. They also point out that asymptomatic oral cavity cancers may be missed, particularly if the clinician is carrying out an inspection to the same degree on all patients, rather than focussing more on high-risk individuals.

McGurk and Scott (2010) have therefore called for improved data collection to enable a mathematical risk model to be produced in the long-term, based on the risk factors outlined in Section 1.9. In the absence of such a model, they suggest that a risk factor checklist

should be completed by patients, with the information enabling the oral health professional to apply their clinical diagnostic skills in a more selective and effective manner. Hashim and co-authors (2019) also mention this risk assessment approach and acknowledge that its effectiveness requires further research. As mentioned earlier, the WHO recommends oral cancer screening among high risk groups (WHO, 2015), while the Report of the Independent Review of Adult Screening Programmes in England (NHS England, 2019) includes screening for oral cancer as part of a dental check-up as an example of screening delivered as part of routine health care.

The effect of the frequency of the COE on the stage of OCC at diagnosis is also an area requiring further research. There is some evidence that repeat examinations may be effective for patients who have considerable previous contact with primary health care (Hashim et al., 2019) and a dose-response association between continuous primary care contact and earlier stage diagnosis of oral cavity cancers has been reported (Prout et al., 1990). Warnakulasuriya (2020) recommends the frequency of follow-up of patients with OPMDs should be based on the individual's risk assessment, with consideration of patient compliance.

As indicated earlier, it can be difficult, at the clinical level, to differentiate between a malignant or potentially malignant oral lesion and one which is innocuous. In other sites of the body where distinguishing the nature of lesions can be problematic, adjunctive tests and technologies can assist in disease detection and discrimination. Consequently, a number of adjuncts, which have been purported to aid the evaluation of oral mucosal lesions, have been developed and are commercially available for use in dental primary care. These Adjunct Tools include vital staining, light-based detection, biomarkers and brush biopsy (Patton et al., 2008; Devji, 2018). However, their potential to aid the detection of OPMDs and early OCCs in the dental primary care setting has yet to be proven (Rashid and Warnakulasuriya, 2015; Warnakulasuriya, 2017).

In summary, although there are many systematic reviews, clinical guidelines and guidance toolkits available on the topic of the examination for oral cavity cancer in dental primary care (Yamada et al., 2015), an initial search of the literature has indicated insufficient evidence and consensus concerning the provision of clear advice in relation to the early OCC detection process. Factors include: the description and extent of the conventional oral examination; whether the approach should be targeted (i.e. for high-risk patients stratified / determined by sociodemographic / behavioural risk factors) or for all patients attending;

the frequency of the assessment / recall period; and the potential use of Adjunct Tools. In addition, the extent to which the guidelines have included the highest quality evidence and quality appraisal is uncertain. The literature associated with these issues will be explored in depth in Chapter 3.

1.12 Current Practice and Perceptions of Primary Care Dental Professionals in Relation to an Oral Cancer Examination

An oral health care professional's knowledge, awareness and perceptions of oral cancer screening in the primary care setting is a crucial element in the effectiveness of the examination process (Aldossri et al., 2020).

A recent study of dental hygienists, conducted in Nova Scotia by Tax and co-workers (2017), found that although respondents believed themselves to be knowledgeable about oral cancer screening, only 13% performed an extra-oral examination and 7% an intra-oral examination for the detection of oral cancer. The study participants identified patient compliance, lack of time and the dentist performing the examinations, as the main barriers in preventing them from undertaking the examinations. They also indicated they would not have the power within the practice to overcome many of the obstacles which prevent them from conducting oral cancer screening (Tax et al., 2017).

Mariño et al (2017) conducted a survey to assess oral cancer screening practices among a wide range of oral health professionals in Victoria, Australia. This included dental specialists, primary care dentists, oral health therapists, dental therapists, and dental hygienists. The study had a very low response rate of under 10% (9% for dentists and 23% for other oral health professionals). Only around half (51%) of the respondents reported conducting oral cancer examinations routinely, but over 90% accepted that opportunistic screening should be carried out on a routine basis. For those not conducting an examination on every patient, the factors influencing whether one was carried out were reported to include the age and medical history of the patient, whether the patient had complained of an oral health problem, and the presence of behavioural risk factors such as smoking and alcohol consumption. Lower levels of oral cancer-related knowledge and confidence in conducting an oral cancer examination were associated with a decreased likelihood of conducting opportunistic screening for this disease (Mariño et al., 2017). Similar findings have been reported by Haresaku et al (2018), where around half (51.4%)

of Japanese dentists and dental hygienists were found to perform oral cancer screening routinely on their patients. Again, there was an association between levels of knowledge and confidence and the likelihood of the Japanese oral health professionals conducting an oral cancer screening. Both studies (Mariño et al., 2017; Haresaku et al., 2018) have recommended the need for additional training programmes related to oral cancer practices for oral health professionals to increase levels of participation in these activities.

A recent survey of dentists in Ontario, Canada (Aldossri et al., 2020) used a 25-item self-administered oral cancer questionnaire. It also had a response rate of around 10%. A high proportion of responding dentists (over 80%) reported always or very frequently carrying out an examination of the mouth for oral cancer in all adult patients, and the percentage rose for those over 45 years of age. Well over 90% of the practitioners indicated they could recognise the common signs of oral cancer and were confident in carrying out a COE, however, confidence levels were much lower (around 20%) with regard to the use of adjunct screening tools. The major barriers to carrying out an oral cancer examination included the lack of a separate fee code for this activity and the lack of clinical guidelines from professional associations (Aldossri et al., 2020). A small proportion of participants mentioned that they were not comfortable palpating a patient's lymph nodes or that they felt that an oral cancer examination would cause patient concern (both 13%).

In the Middle East, a number of studies have assessed oral cancer screening awareness, opinions and practices of primary care dentists. This included one in Kuwait (Nazar et al., 2019) and one in UAE (Hashim et al., 2018). Cross-sectional study designs were used in both studies, with response rates of 71% and 80% respectively. The main shared finding was that all dentists had knowledge of the major risk factors associated with oral cancer. Furthermore, in Kuwait (Nazar et al., 2019), many of the dentists reported that they were aware of the most common sites, shapes and occurrence of oral cancer. By contrast, in the UAE, only 30% of the participants reported awareness of the most common sites (Hashim et al., 2018). In terms of screening practice, Nazar et al (2019) reported more than half of the dentists in primary health care reported conducting examination for their patients; and 81% of the dentist routinely referred their patients to a specialist. However, a lack of confidence in conducting a visual screening was reported by dentists in UAE (Hashim et al., 2019). The majority of dentists in both countries (92.4% in Kuwait and 84.9% in UAE) expressed an interest in attending continuing education related to oral cancer. One of the major limitations in both studies was the involvement of dentists alone, without inclusion

of other oral health professionals such as oral therapists and dental hygienists who can also contribute to the early detection of oral cancer. In Oman, no studies have been conducted to assess oral health professionals' awareness, opinions, attitudes and practices in relation to oral cancer detection. A very recent study has, however, reported on the effect of a head and neck awareness campaign among patients (Al-Dhahli et al., 2020).

In summary, most of the studies on this topic area have used self-administered questionnaires and have had relatively low response rates. Some have included different members of the primary dental health care team, while others have focussed on dentists. Many of the investigations have lacked a behavioural theoretical approach in the design and analysis of the questions. The levels of knowledge, confidence and practice related to carrying out an examination for the early detection of oral cancer varied in different parts of the world, and in some countries, including Oman, there has been a lack of research in this area.

1.13 Perceptions of Patients in Relation to an Oral Cancer Examination When Attending Dental Primary Care

Incorporating patients' views when developing clinical guidelines is important because patients' needs and preferences are potential barriers to implementation (Gagliardi et al., 2011; Kastner et al., 2015; Armstrong et al., 2018). Previous studies have looked at dental patients' views on oral cancer (Warnakulasuriya et al., 1999; West et al., 2006). Some have focused on patient awareness of oral cancer, with variable findings, while Awojobi and co-authors (2012) have also explored views on screening services. They have reported that many participants had a positive opinion about screening and showed willingness to accept help from dental practitioners to reduce their risk of oral cancer.

These findings are in contrast to a qualitative study on patients' views on oral cancer screening in dental settings carried out in the UK (Zohoori et al., 2012). They conducted a focus group among patients who smoked cigarettes and / or drank alcohol to identify their knowledge of oral cancer and factors contributing to the uptake of oral cancer screening. They found that the participants had a low level of knowledge related to oral cancer, including its signs and symptoms. Furthermore, participants reported that if they observed signs and symptoms of oral cancer, they would seek help from a health professional - but preferring to attend a medical practitioner rather than a general dental practitioner. This

was due to a) the expense of dental visits and b) a perception of this being outside the scope of the professional role of the dentist: “they are tooth specialists, not mouth specialists”.

There were further barriers related to geographical access, and perceptions around a dentist’s ability to refer to specialists and prescribe medicine. The participants also did not utilize the offer that was provided to them to have a free oral examination (Zohoori et al., 2012). This study shows that patients’ views can be at odds with recommendations. However, the study had some limitations: all participants were either smokers or drinkers (or both) which excludes others at possible increased risk of getting oral cancer such as individuals with low intake of vegetables and fruits and weakened immune systems (Ram et al, 2011; American Cancer society, 2018; Cancer Research UK, 2018; Canadian Cancer society, 2020). In addition, the study was not informed by analysis based on psychological models or theories of behaviour. There is evidence from the literature (Rawahi, Asimakopoulou & Newton, 2017) that the use of such psychological models for deriving findings from qualitative work helps in a rigorous extraction of factors important for uptake of evidence-based recommendations.

The lack of consensus on acceptability of oral cancer screening in the dental setting (Awojobi et al., 2012; Zohoori et al., 2012) may be due in part to a) the setting, b) the patient groups or c) the methods (quantitative vs qualitative), but nevertheless validates further exploration.

Overall, there are variable interpretations of the acceptability of comprehensive screening for oral cancer in dentistry, little or no work looking at different cultures / countries, and a variable and limited picture with respect to the application of psychological / behavioural theory in designing research questions and extracting themes, which is now viewed as essential.

1.14 Summary

Oral cavity cancer is a public health problem, representing the 16th most common cancer globally, with approximately 355,000 new cases and over 177,000 deaths per year (Ferlay et al., 2015; Bray et al., 2018). Incidence and mortality rates vary greatly across the world, and in some countries, such as those in South East Asia and the Pacific Islands, it is one of the most common cancers. There has been limited improvement in 5-year survival from

oral cavity cancer in the past few decades (Pulte and Brenner, 2010) and a meta-analysis has confirmed that delay from first symptom to referral for diagnosis is risk factor for advanced stage presentation and subsequent poorer survival (Seoane et al., 2016). The INHANCE consortium has facilitated investigation and identification of the major risk factors for oral cavity cancer (Winn et al., 2015). It has therefore been surmised that improvement in incidence and death rates should be possible through a combination of preventive interventions and examination of the mouth for oral cancer and OPMDs.

As the oral cavity is one of the most accessible parts of the human body, there has been much interest in screening for oral cancer. However, no country has set up a national screening programme for the disease. Reasons for this include the relatively low incidence of OCC in most countries, lack of evidence that such a programme would reduce mortality rates, uncertainty about the natural history of OPMDs and lower dental primary care attendance rates among those at higher risk of OCC. Instead, in many countries it is recommended that an examination of the oral cavity for malignant or potentially malignant lesions should form part of a routine check-up in dental primary care. Although there have been a number of systematic reviews and numerous clinical guidelines on the topic of the COE, there are still uncertainties around a number of factors associated with the examination process. These include: a) the method of conducting the conventional oral examination, b) the target population, i.e. high risk or universal approach, c) the frequency of the oral cancer screening procedure, and d) the extent to which Adjunct Tools are used.

The literature review found that the practice of carrying out an oral examination in dental primary care varied among oral health professionals. Many of the findings were based on surveys with low response rates. While some practitioners felt knowledgeable about the examination process, others called for evidence-based clinical guidelines and clarity on issues such as the use of adjuncts. The issue of the perceptions of patients was also raised in some studies. However, there is limited literature and variable interpretation of the views of patients with regard to the acceptability of a COE in dental primary care. In the research involving both the dental professionals and the patients, there is limited work exploring the effect of different cultures and / or countries on potential barriers and facilitators to the COE, and the inclusion and use of behavioural theory in designing research questions and analysing findings is variable.

This thesis aims to explore further the gaps identified in the literature review, and the aims, research questions and objectives are set out in the following chapter.

Chapter 2: Aims and Objectives

This thesis evaluates the evidence-base in relation to early detection and screening of oral cavity cancer; and assesses factors associated with implementation in primary care dental settings. Three main studies were conducted in order to achieve these aims and are reported in chapters 3, 4, and 5.

2.1 Study 1: Systematic Overview of Clinical Guidelines and Systematic Reviews in Relation to Oral Cavity Cancer Early Detection / Screening (Chapter 3)

2.1.1 Aim

To assess pre-existing evidence and identify best practice for the early detection / screening for oral cavity cancer, undertaken by oral health care professionals in primary dental care.

2.1.2 Research Questions

What methods / approach for early detection / screening of OCC are considered best practice for oral health care professionals when assessing patients attending primary care dental health care settings, including:

1. What is the effectiveness of the conventional oral examination?
2. Should the approach be population, opportunistic, or targeted based on risk factors?
3. With what frequency should the assessment be undertaken?
4. Should Adjunct Tools be used in addition to the conventional oral examination?

2.1.3 Objectives

1. To systematically search for evidence including systematic reviews and clinical guidelines in relation to the early detection / screening for OCC in primary care dental settings.
2. To appraise the quality of the evidence using recognised and validated critical appraisal tools.
3. To describe and rate the evidence in relation to the effectiveness of the clinical examination / assessment process including; the applicability to

dental settings; the approach (e.g. opportunistic, universal, targeted); the frequency of assessment; and the use of Adjunct Tools.

4. To synthesize the evidence of extracted data from systematic reviews and clinical guidelines in order to identify best practice for the early detection / screening of OCC in primary care dental settings.

The synthesised results from the systematic overview conducted in this first study will guide the conduct of the qualitative studies (Studies 2 and 3), with the oral health care professionals and patients respectively.

2.2 Study 2: Qualitative exploration of the perceptions of oral health care professionals on early detection/ screening for OCC in primary care dental settings in Scotland and Oman (Chapter 4)

2.2.1 Aim

To explore which components of best practice evidence, synthesized in the first study, were being implemented by oral health care professionals (OHCPs). A supplementary aim was to make a cross-country / inter-cultural comparison between Oman and Scotland.

2.2.2 Research Questions

1. What is the current practice of OHCPs in relation to early detection / screening of OCC?
2. What are the barriers and the facilitators of implementation of best practice evidence in relation to OCC early detection / screening in primary care dental settings?
3. How do these OHCP experiences and views compare between those from Oman and Scotland?

2.2.3 Objectives

1. Gain ethical approval to access and recruit patients in the primary health care settings in Oman and Scotland.
2. Design a semi-structured interview guide incorporating open-ended and fixed response questions based on the best evidence identified in the systematic overview.

3. Collect and collate data from representative groups of OHCP working in primary health care dental settings in both countries.
4. Analyse data using Behaviour Change Wheel (COM-B) psychological theory.
5. Report findings and discuss in relation to evidence-based practice in the four dimensions of screening / early detection for oral cavity cancer, namely: conventional oral examinations, role of targeting, frequency of assessment, and use of adjuncts.
6. Compare findings between Oman and Scotland.

2.3 Study 3: Patient views on early detection / screening for OCC in dental settings in the Sultanate of Oman and Scotland (Chapter 5)

2.3.1 Aim

To explore the views of adult patients attending primary care dental settings in relation to oral cancer early detection / screening. A supplementary aim was to make a cross-country / inter-cultural comparison between Oman and Scotland.

2.3.2 Research questions

1. What are patients' experiences of previous and current practices in relation to early detection / screening for oral cavity cancer within primary care dental settings?
2. What are the barriers / facilitators from the patient perspective to implementing OCC early detection / screening in primary dental care settings?
3. How do these patient views and experiences compare between Oman and Scotland?

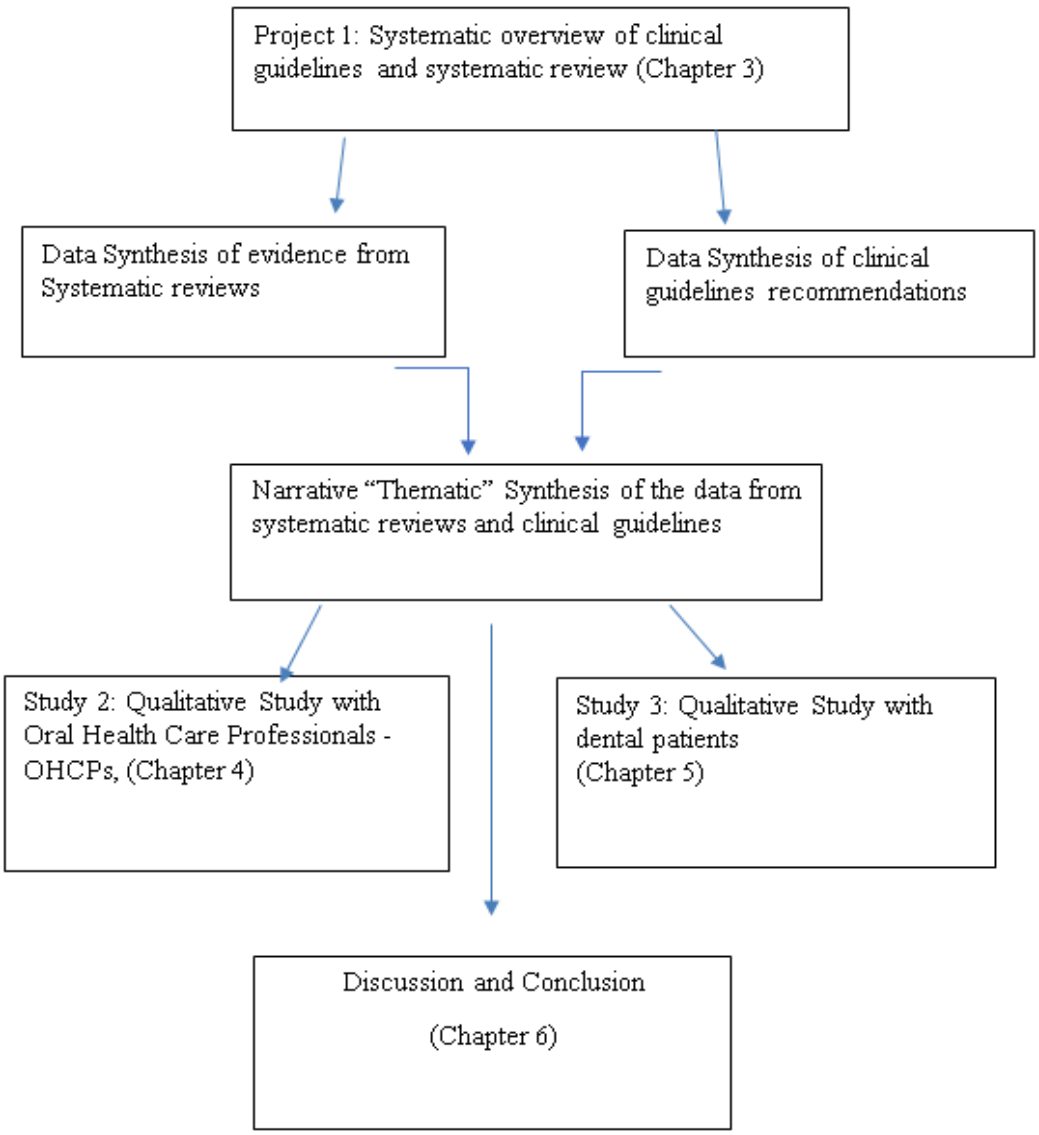
2.3.3 Objectives

1. Gain ethical agreement and consent from research institutions in relation to this study: Ministry of Health (Oman)
2. Design a semi-structured interview guide incorporating open-ended and fixed response questions on implementation of the best evidence identified in the systematic overview
3. Collect and collate interview data from a representative group of patients attending primary health care dental settings who have consented to participate.

4. Analyse data using psychological theory such as COM-B and Theoritical Domains Framework (TDF).
5. Report findings and discuss in relation to evidence-based practice in the four dimensions of screening / early detection for oral cavity cancer, namely: conventional oral examinations, role of targeting, frequency of assessment, and use of adjuncts.
6. Compare findings between Oman and Scotland.

The thesis Discussion (Chapter 6) summarises and synthesises the findings across the three studies, and discusses the strengths and limitations of the thesis. Finally, recommendations for intervention development, practice, policy, and research will be proposed. An overview of the aims and objectives for each project is presented below in Figure 2.1.

Figure 2.1 Overview of Chapters in this thesis



Chapter 3: Systematic Overview of Clinical Guidelines and Systematic Reviews in Relation to Oral Cavity Cancer Early Detection / Screening

3.1 Introduction

The initial search and review of the peer-reviewed literature and clinical guidelines (Chapter 1) indicated there were many clinical guidelines from across the world which had collated evidence and made recommendations in relation to early detection / screening for oral cavity cancer. Initial scoping indicated there were some differences and inconsistencies in the guidelines. To navigate and provide clarity for oral health care professionals working in primary care settings, a systematic overview approach appraising this collated evidence-base within clinical guidelines was proposed. This would involve systematically searching, appraising the quality, and synthesising the findings to identify the evidence and best practice in relation to the early detection / screening process. The following aspects or dimensions of the early detection / screening process were identified by the author in the scoping review process – a taxonomy that will be used throughout the thesis: i) the nature / description of the assessment (conventional oral examination; COE); ii) whether the approach should be a targeted (i.e. to high-risk patients stratified / determined by sociodemographic / behavioural risk factors) versus a population (i.e. universal to all patients) approach; iii) the frequency of the assessment (recall / review interval); and iv) the use of the Adjunct Tools (e.g. vital staining, light-based detection, biomarkers, and brush biopsy), In addition, the extent to which the clinical guidelines have included the highest quality evidence, and indeed have adopted a robust literature search, and quality appraisal is uncertain. Moreover, during the scoping process, many systematic reviews were identified which had reviewed aspects of the early detection / screening process.

Therefore, there is a need to assess the relevant clinical guidelines and systematic reviews in this field using a systematic approach to provide clarity for primary care oral health care teams on the best early detection / screening practice for OCC and potentially malignant disorders.

Clinical guidelines also known as clinical practice guidelines or clinical guidance are defined as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances." (Lohr and Field, 1992). They are intended to provide recommendations on how to provide health care services – with the twin aims of improving quality of care and patient outcomes. Increasingly, clinicians and care providers are having to deal with numerous and sometimes differing or contradictory guidelines (Graham and Harrison, 2005). The quality of clinical guidelines is variable and can have a questionable evidence base - with poor guidelines having the potential to lead to the use of interventions which are neither effective nor cost-effective and could harm patients (Feder et al., 1999).

Systematic reviews are defined as reviews of the literature or evidence-base which are undertaken in a methodical way to avoid potential selective biases of traditional narrative literature reviews (Petticrew and Roberts, 2006). Systematic reviews are usually focused on a specific topic or question and methods were first developed for reviewing and collating evidence of effectiveness from randomised controlled trials of clinical interventions although methods are being adapted to other settings and study types (Campbell Collaboration, 2020; Cochrane Collaboration, 2020). There are three core aspects of systematic reviews - systematic and comprehensive search of international literature; quality appraisal of identified included studies; and synthesis of findings of included studies (Petticrew and Roberts, 2006; Popay et al., 2006).

Systematic overviews, sometimes also known as "umbrella reviews" (Aromataris et al., 2015), are systematic reviews of systematic reviews or systematic reviews of clinical guidelines. These overviews are particularly helpful for policymakers to inform decision making – resolving uncertainties or debates in guidance or evidence; and when the quantity of evidence or materials is vast and there already has been several attempts to synthesis and distil from perhaps different perspectives (e.g. different settings or countries (Silva et al., 2012; Aromataris et al., 2015).These overviews have a similar structure to systematic reviews of intervention or observational studies, but include "systematic reviews" as the studies rather than including the primary studies; and are conducted where a number of intervention systematic reviews already exist (Silva et al., 2012).This approach has also been applied to clinical guidelines to utilise these sources of evidence, where randomised controlled trials or systematic reviews perhaps do not exist, or to cover areas of practice not suited to randomised trial methodology. Examples of overviews include an overview of

clinical guidelines in relation to osteoarthritis (Brosseau et al., 2014) and an overview of Cochrane reviews in relation to endometriosis management (Brown and Farquhar, 2014).

Thus far, to the author's knowledge, this systematic overview approach has not been applied to the topic of early detection / screening of oral cancer; nor have both systematic reviews and clinical guidelines been systematically reviewed together within the one overview.

3.2 Aims and Objectives

3.2.1 Aim

To assess pre-existing evidence and identify best practice for the early detection / screening for oral cavity cancer, undertaken by oral health care professionals in primary dental care.

3.2.2 Research Questions:

What methods / approach for early detection / screening of OCC are considered best practice for oral health care professionals when assessing patients attending primary care dental health care settings, including:

- what is the effectiveness of the conventional oral examination?
- should the approach be population, opportunistic, or targeted based on risk factors?
- with what frequency should the assessment be undertaken?
- should Adjunct Tools be used in addition to the conventional oral examination?

3.2.3 Objectives:

- To systematically search for evidence including systematic reviews and clinical guidelines in relation to the early detection / screening for OCC in primary care dental settings.
- To appraise the quality of the evidence using recognised and validated critical appraisal tools.

- To describe and rate the evidence in relation to the effectiveness of the clinical examination / assessment process including; the applicability to dental settings; the approach (e.g. opportunistic, universal, targeted); the frequency of assessment; and the use of Adjunct Tools.
- To synthesize the evidence of extracted data from systematic reviews and clinical guidelines in order to identify best practice for the early detection / screening of OCC in primary care dental settings.

3.3 Methods

Methods for the development of this overview were developed and adapted from generic guidance on systematic overviews / umbrella reviews (Silva et al., 2012; Aromataris et al., 2015), and on guidance on undertaking individual systematic reviews (Cochrane Collaboration, 2020), as well as from reporting checklists – including the Preferred Reporting Items for Systematic review and Meta-Analysis Protocols (PRISMA-P) 2015 checklist (Shamseer et al., 2015), and the Meta-analysis of Observational Studies in Epidemiology (MOOSE) checklist (Stroup et al., 2000). Other systematic overviews of systematic reviews (Haran et al., 2014; Asamoah et al., 2017; Leigh-Hunt et al., 2017), or overviews of clinical guidelines (Huang et al., 2013; Haran et al., 2014) were also consulted for approaches. To the author's knowledge, this overview was the first overview to combine a systematic overview of both clinical guidelines and systematic reviews. It was undertaken in parallel with a similar overview on primary prevention of oral cancer undertaken by a colleague PhD student (Mathur et al., 2015).

The protocol for this overview study was published in the journal *Translational Research in Oral Oncology* (Al Bulushi et al., 2016), and was reported against the PRISMA-P checklist.

No ethics approval was required for this study.

3.3.1 Eligibility Criteria

3.3.1.1 Types of Studies

This study includes evidence from systematic reviews and clinical guidelines in relation to early detection / screening for OCC in primary care dental settings. Both clinical guidelines

and systematic reviews are likely to include specific recommendations and evidence on OCC early detection / screening for dental health care professionals in primary care settings. Our search included peer-reviewed and grey literature and it was not restricted to any language. The systematic reviews were searched from 1946 to current date and the clinical guidelines sought from 2000. Case studies / reports, published abstract only and systematic review protocols were excluded.

3.3.1.2 Types of Participants

The population group for this study is the adult population (including high-risk individuals) who attend primary health care dental settings.

3.3.1.3 Types of Interventions

This includes early detection / screening interventions for detecting OCC by dental health care professionals / teams in primary care dental settings. These interventions include conventional clinical oral examinations along with other adjunct methods (such as vital rinsing / staining, light-based detection, blood and saliva biomarker analysis and brush biopsy).

3.3.1.4 Types of Settings

This study focused on applicability to primary care (also known as community) dental settings.

3.3.1.5 Study Outcomes

1. Evidence for effectiveness of interventions (e.g. does early detection / screening decrease the incidence rates of OCC; does early detection / screening improve the stage of diagnosis and / or improve mortality rates; what could be the harms of the screening; and is it cost effective?).

2. Description of an evidence-based intervention (i.e. the clinical oral examination; frequency of the assessment; use of adjunct methods and whether the approach should be population, opportunistic or targeted based on risk factors).

3.3.2 Information Sources

3.3.2.1 Databases

A systematic overview for clinical guidelines and systematic reviews in the worldwide literature was performed in December 2017 with the support of a medical subject librarian (HW-A) in the following databases:

1. Cochrane Library from 1966 to present,
2. Medical Literature Analysis and Retrieval System Online (MEDLINE) from 1946 to present,
3. Excerpta Medical dataBASE (EMBASE) from 1947 to present,
4. Web of Science Core Collection: Citation Indexes from 1900 to present,
5. PubMed (a free search engine accessing primarily the MEDLINE database of references and abstracts on life sciences and biomedical topics) from 1946 to present,
6. SCOPUS (a bibliographic database containing abstracts and citations for academic journal articles) from 1966 to present,
7. Turning Research into Practice (TRIP) from 2000 to present.

3.3.2.2 Other Sources

Professional organizations' / associations' websites from around the world were searched for additional global clinical guidelines in relation to OCC early detection. A List of professional organizations / associations is included in Appendix 3.1. Despite the limitations in searching on Google in relation to language, geographical biases and lack of replicability, a list of target phrases was used to run in Google searches to discover grey literature in the form of web-published guidelines from official bodies. A list of phrases used for Google / Google Scholar search are included in Appendix 3.2. The reference lists of the selected papers were hand searched for additional studies. In addition, citation searches were conducted in Google Scholar and Web of Science of the selected papers to identify further systematic reviews and clinical guidelines.

3.3.3 Search Strategy

A search strategy was developed with the medical librarian and a clinical expert in the area of OCC (JG). Multiple databases were searched with the following and related terms: "cancer", "neoplasm", "oral potentially malignant disorders", "oral", "mouth" "head and neck", "buccal", "lips", "tongue", "assess", "screen", "inspect" and "exam". The terms

were followed by appropriate truncation symbols (for example * or $). For further refinement Boolean operators such as (AND/OR proximity) were used. The search was limited to titles/abstracts rather than full bibliographic records. The search results in MEDLINE and EMBASE were limited to systematic reviews, using the SIGN search filter, or clinical guidelines, using the Texas School of Public Health search filter. These search filters are pretested strategies that identify the higher quality evidence which are indexed in the major medical databases. The sample search strategy in MEDLINE is appended (Appendix 3.3).

3.3.4 Data Management

All the search results including bibliographies, citation and references were managed through a reference manager 'Mendeley'. The collected records (systematic reviews and clinical guidelines) were evaluated independently by two investigators from the research team (NMB for all and one from LMDM, JG, AR, or DIC). The evaluation included reviewing titles, abstracts, and full text of articles. Duplicate records were removed. A PRISMA four-phase flow diagram was designed to indicate the search process. The diagram mapped out information about the number of records identified in the literature searches based on inclusion criteria, number of studies included and excluded and the reasons for exclusion. The final selected systematic reviews and clinical guidelines were assessed for quality and risk of bias. If discrepancies were identified at any stage, these were resolved by discussion amongst all members of the review team. This methodological stage was adapted from the Cochrane Collaboration (Higgins and Green, 2011).

3.3.5 Data Extraction

The Cochrane Collaboration data collection form was adopted, modified and pilot tested to meet study specified requirements (Higgins and Green, 2011). The piloted data extraction form was used independently by two investigators (NMB for all and one from LMDM, JG, AR, or DIC). The following information were extracted from the included systematic reviews and clinical guidelines: authors/organization (e.g. Cochrane, ADA), date of publication, number / type of studies included, interventions, outcomes, main results and conclusions – including recommendations which included the level of evidence used within the systematic review and clinical guidelines. A data extraction form for the

systematic review was developed (Appendix 3.4). A similar form was used to extract the data from the clinical guidelines (Appendix 3.5). Any missing information from the reports were recorded as 'not described' in the data extraction forms. Discrepancies were resolved through discussion by the review team.

3.3.6 Quality Assessment and Risk of Bias

3.3.6.1 Systematic Reviews

The methodological quality and the risk of bias of the included systematic reviews were assessed by three reviewers (NMB for all plus supervisors in pairs LMDM and JG or AR and DIC). Reviews were performed in triplicate because most reviewers were new to the process and recently developed appraisal tools were being used. All systematic reviews were assessed using two different tools: AMSTAR – A measurement tool to assess the methodological quality of systematic reviews (Shea et al., 2007) and the ROBIS – risk of bias in systematic reviews (Whiting et al., 2016).

The AMSTAR tool is a valid and reliable tool (Shea et al., 2007). It consists of 11 items each with the options "Yes", "No", "Can't Answer" or "Not Applicable" to complete. It assesses the quality of the key steps of systematic reviews including comprehensive unbiased search approach, duplicate study selection and data extraction, quality assessment, synthesis, as well as *a priori* design (Shea et al., 2009). The maximum score on AMSTAR for a systematic review is 11; scores of 0-4 are considered low quality; scores of 5-8 moderate quality; and scores of 9-11 are high quality systematic reviews.

In addition, the more recently developed ROBIS tool (Whiting et al., 2016) was used – this tool is complementary to AMSTAR and specifically assesses risk of bias in systematic reviews. This tool is completed in three phases: (1) assess relevance (optional), (2) identify concerns with the review process, and (3) judge risk of bias. **Phase 1 -** is optional – it concerns study data. As this was collected via the data extraction forms, this phase of the ROBIS assessment was not undertaken. **Phase 2 -** covers four domains through which bias may be introduced into a systematic review: study eligibility criteria; identification and selection of studies; data collection and study appraisal; and synthesis and findings. **Phase 3 -** assesses the overall risk of bias in the interpretation of review findings and whether this considered limitations identified in any of the phase 2 domains. Signalling questions are included to help judge concerns with the review process (Phase 2) and the overall risk of

bias in the review (Phase 3); these questions flag aspects of review design related to the potential for bias and aim to help assessors judge risk of bias in the review process, results, and conclusions (Whiting et al., 2016)

The outputs of the AMSTAR and ROBIS tools were compared, and the items/domain which focused on quality appraisal was prioritized in defining overall quality of systematic reviews and in the data synthesis.

3.3.6.2 Clinical Guidelines

The quality of the clinical guidelines was assessed by three reviewers (NMB for all plus supervisors in pairs LMDM and JG or AR and DIC) using the AGREE II instrument (Brouwers et al., 2010). This tool consists of 23 key items organized within six domains followed by two global rating items ("Overall Assessment"). Each domain captures a unique dimension of guideline quality. **Domain 1 -** Scope and Purpose is concerned with the overall aim of the guideline, the specific health questions, and the target population (items 1-3). **Domain 2 -** Stakeholder Involvement focuses on the extent to which the guideline was developed by the appropriate stakeholders and represents the views of its intended users (items 4-6). **Domain 3 -** Rigour of Development relates to the process used to gather and synthesize the evidence, the methods to formulate the recommendations, and to update them (items 7-14). **Domain 4 -** Clarity of Presentation deals with the language, structure, and format of the guideline (items 15-17). **Domain 5 -** Applicability pertains to the likely barriers and facilitators to implementation, strategies to improve uptake, and resource implications of applying the guideline (items 18-21). **Domain 6 -** Editorial Independence is concerned with the formulation of recommendations not being unduly biased with competing interests (items 22-23). For this study, the overall score of each guideline and overall score for Domain 3 were used to compare between guidelines. The maximum score on AGREE II is 7, and scores of 1-2 indicate that the clinical guideline is considered of low quality, scores 3-5 is of moderate quality; and scores 6-7 that the clinical guideline is of high quality.

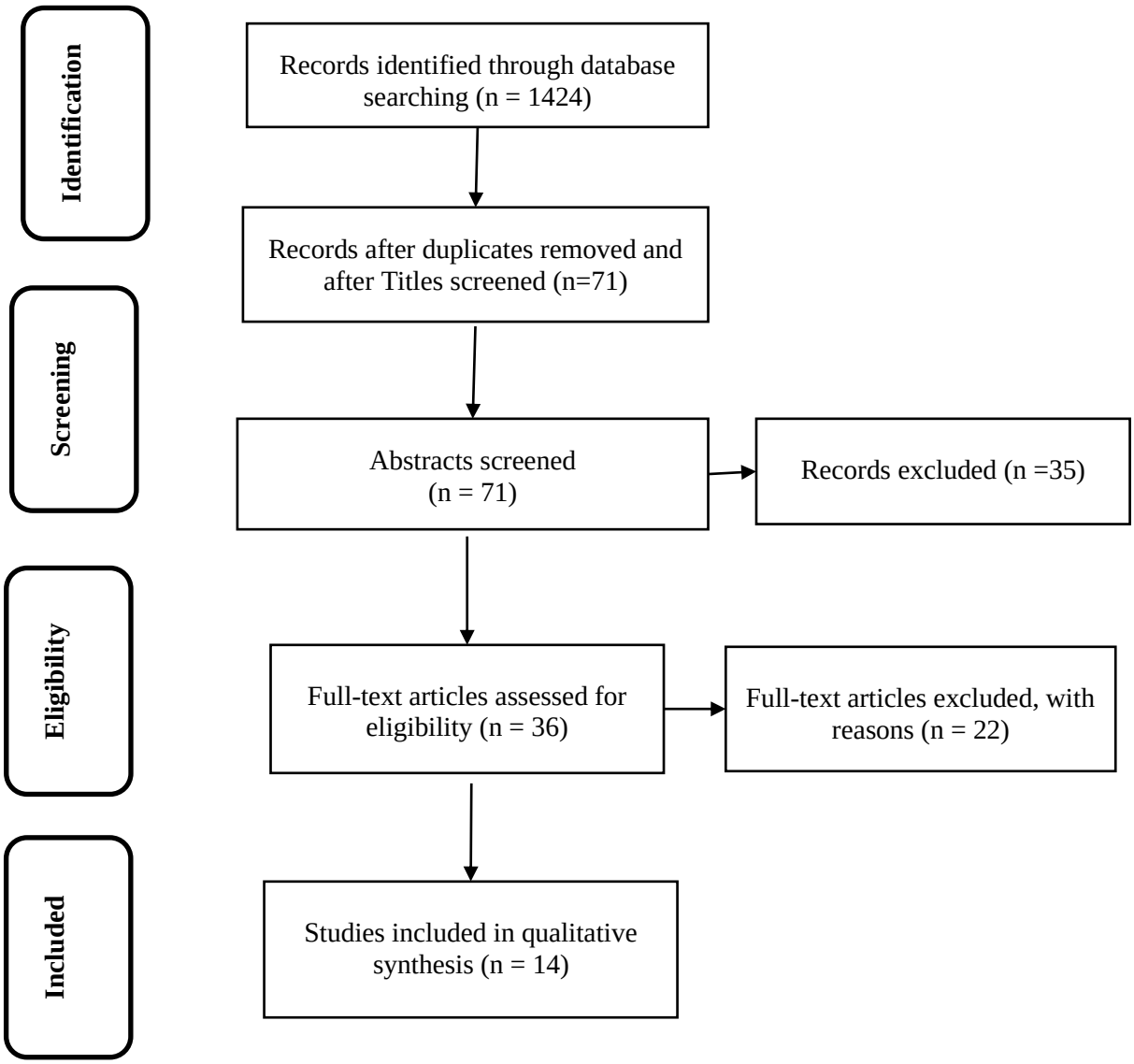
The scores for each domain for each of the three reviewers were compared and consensus score for that domain was agreed. These individual domain scores were used to calculate an overall AGREE II score for the clinical guideline as per AGREE II methods (Brouwers et al., 2010). An MS Excel database was used to collate data and record consensus scores.

3.4 Results

3.4.1 Search Results – Systematic Reviews

The systematic review search strategy initially yielded 1424 papers (Figure 3.1). After removal of duplicate studies and title screening the number reduced to 71 systematic reviews. Abstract screening further reduced this by excluding 35 papers, and so 36 systematic reviews were identified as requiring full text review. Of these, 14 systematic reviews met the inclusion criteria for this overview (Appendix 3.6). The reference list of excluded full text records (n=22, with reasons) is included in Appendix 3.7.

Figure 3.1 PRISMA Flow Diagram for Systematic Reviews

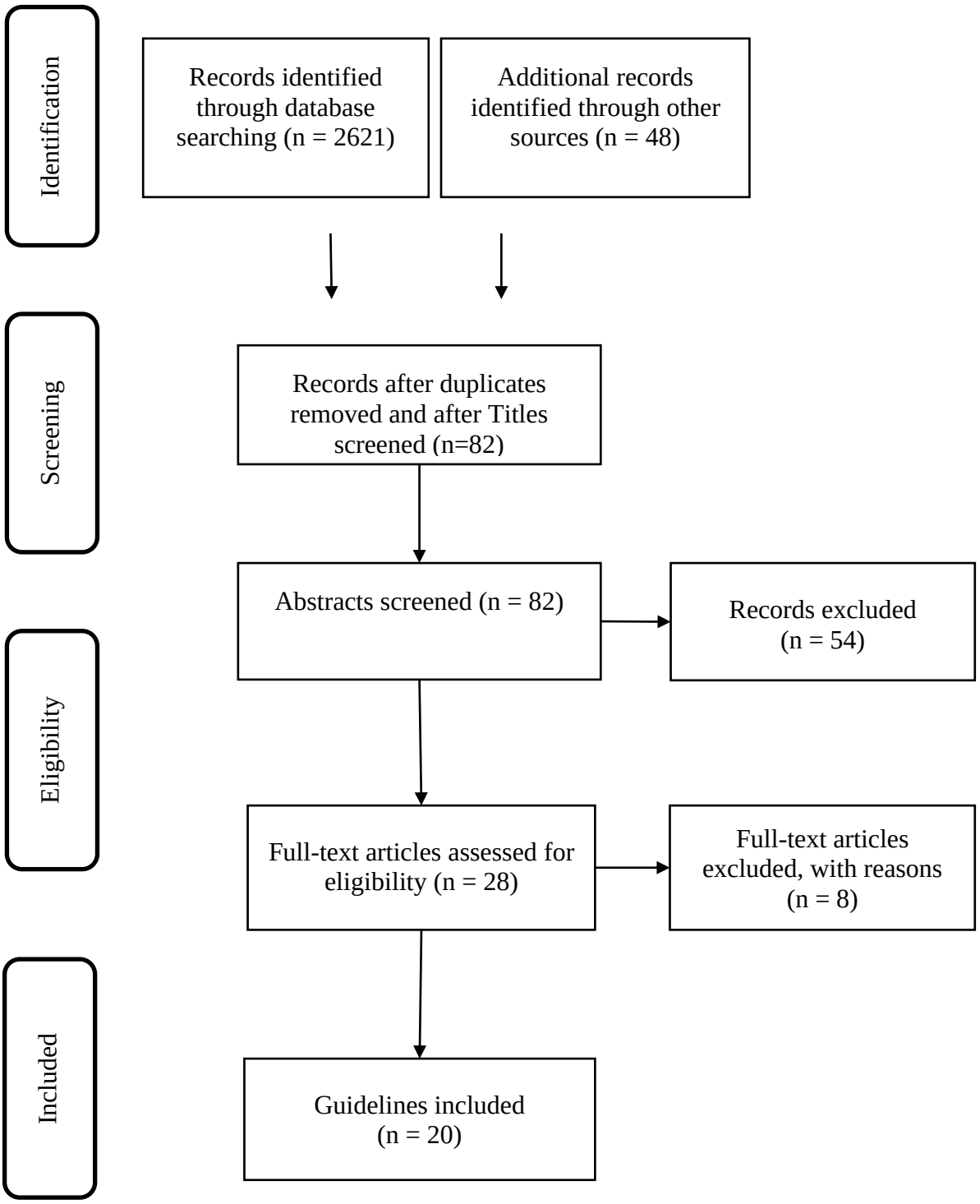


3.4.2 Search Results – Clinical Guidelines

The search strategy identified 2621 clinical guidelines (Figure 3.2). Additionally, 48 potentially relevant clinical guidelines had been previously identified from initial scoping search and from supervisors obtained from other sources (these were all largely identified by the search and duplicates were removed accordingly). After removal of duplicates and title screening, the number reduced to 82 clinical guidelines. After abstract screening, 28 clinical guidelines were retrieved for full text review from which 20 met the inclusion criteria (Appendix 3.8). An additional clinical guideline document was included which was

an update of a previous guideline so the final included number did not change. The reference list of excluded records (n=8 with reasons) is included in Appendix 3.9.

Figure 3.2 PRISMA Flow Diagram for Clinical Guidelines



3.4.3 Characteristic of Included Systematic Reviews

The characteristics of the included systematic reviews are presented in Table 3.1. There were 14 systematic reviews which met the inclusion criteria, half (n=7) of which had been published between 2012 and 2017. Of these recent reviews, there were three published as part of the Cochrane Collaboration and one under the auspices of the American Dental Association (as part of their updated clinical guidelines in 2017). The studies consistently drew on the same single randomized controlled trial in the literature (Sankaranarayanan et al., 2005).

Ten of the systematic reviews assessed the effectiveness of the clinical oral examination, while nine reviews investigated the additional role of Adjunct Tools. Two of the reviews were focused on recall intervals and one was on a variety of screening models and community-based intervals. Most reviews (n=7), where specified, included studies in the dental primary care / community settings. Outcomes considered were both oral cavity cancer and oral potentially malignant disorders (13). Reducing mortality was another outcome in three reviews (Truman et al., 2002; Downer et al., 2006; Brocklehurst et al., 2013).

Table 3.1 The characteristics of included systematic reviews

Study ID	Organisation	Number/Type of Study Included	Type of Synthesis	Interventions/ Comparison	Settings	Outcomes
Gray *et al.*(2000)	West Midlands & Evaluation Services	15 studies – each study was a case series, 1 prospective cohort study	Narrative synthesis (economic analysis)	COE/Adjunct	Secondary care and Primary care	OCC
Truman *et al.*(2002)	Independent, nonfederal Task Force on Community Preventive Services	19 studies (reported in 24 articles)	Narrative synthesis	Population/ Universal	n/s	OCC + OPC (+ stage) Mortality
Patton. (2003)	Department of Dental Ecology, School of Dentistry, University of North Carolina.	21 related to COE, 10 related to adjunctive technique (adj tech), 2 related to COE augmented by Adj tech.	Narrative synthesis	COE/Adjunct	Community	OPMD
Davenport *et al.* (2003)	Health Technology Assessment HTA NHS R&D HTA Programme	Caries = 25 studies Periodontal disease = 9 studies Oral cancer = 2 studies	Grouping studies by statistical significance and direction of effect	Recall/frequency	n/s	OCC OPMD
Downer *et al.* (2004)	Manchester University Dental School	7 papers describing 8 studies included	Meta-analysis	COE/Adjunct	Community/population screening	OPMD OCC

Study ID	Organisation	Number/Type of Study Included	Type of Synthesis	Interventions/ Comparison	Settings	Outcomes
Downer *et al.* (2006)	Eastman Dental Institute for Oral Health Care Sciences, University college London.	28 articles	Narrative synthesis	COE/Adjunct	Primary care	OCC (+stage) OPMD morbidity, mortality, survival,
Patton et al. (2008)	University of North Carolina,	23 articles	Narrative synthesis	COE/Adjunct	Primary care	OPMD, OCC
Epstein *et al.* (2012)	Cedars Sinai Medical Center, LA.	24 (observational Studies)	Meta-analysis	COE/Adjunct	Various study settings	OPMD (dysplasia) OCC.
Riley *et al.* (2013)	Cochrane Collaboration	1 RCT	Narrative synthesis	Recall/frequency	Primary care	12 & 24 months OPMD OCC (+stage) OHQoL.
Walsh *et al.* (2013)	Cochrane Collaboration	13 studies	Narrative synthesis	COE/Adjunct	Different settings used the interventions	OPMD, OCC
Brocklehurst *et al.*(2013)	Cochrane Collaboration	1 RCT	Meta-analysis was not applicable (less than 3 trials)	COE/Adjunct	Clinical settings (under type participants)	OCC (mortality) OCC, OPMD (incidence + stage) Adverse effects Costs
Warnakulasuriya *et al.*(2015)	Kings College London	16 (OC/pre-cancer screening studies)	Narrative description / synthesis	COE/Adjunct	Varies (such as medical facilities, dental practice, industrial settings... etc.)	OCC OPMD

Study ID	Organisation	Number/Type of Study Included	Type of Synthesis	Interventions/ Comparison	Settings	Outcomes
Carreras-Torras and Gay-Escoda. (2015)	School of Dentistry, University of Barcelona (Spain)	60 articles (1 meta-analysis, 17 systematic reviews, 35 prospective studies, 5 retrospective studies, 1 consensus and 1 semi- structured interviews.	Narrative synthesis	COE/Adjunct	n/s	Early diagnosis, OPMD, OCC (stage)
Lingen *et al.* (2017)	American Dental Association	38 articles	Narrative synthesis	COE/Adjunct	Primary care	OPMD

COE=Clinical Oral Examination; OCC= Oral Cavity Cancer; OPC= Oral and Pharyngeal Cancer; OPMD = Oral Potential Malignant Disorders; RCT=Randomized Control Trial; OC= Oral Cancer; n/s= not stated.

3.4.4 Characteristic of Included Clinical Guidelines

There were 20 clinical guidelines that met the inclusion criteria (Tabel 3.2). They were from the following countries: 10 from UK, six from US, one from New Zealand, two from Canada and one from South Australia. Around half (n=9) of the clinical guidelines were published after 2010.

The guidelines covered different areas such as, recall, prevention, assessment, diagnosis and management, early detection, oral health assessment and review, and screening.

The majority of the clinical guidelines covered one or more areas of the four themes (clinical oral examination, use of adjuncts tools, frequency of screening and target population). For example, 12 of the 20 clinical guidelines covered the clinical oral examination, eight discussed the use of Adjunct Tools for early detection / screening of OCC, 10 gave recommendations in relation to recall / frequency of screening, and 12 discussed which target population should be examined in relation to OCC.

Table 3.2 Characteristics of Clinical Guidelines (n=20)

Study	Organisation/ Association	Title of Clinical Guideline	Country	4 themes			
				COE	Adjuncts	Frequency	Target pop.
ACS (2003)	American Cancer Society	American Cancer Society Guidelines for the early detection of cancer.	USA	Y	N	Y	Y
GU-GDS (2003)	University of Glasgow-Glasgow Dental School	Oral Cancer prevention and detection	UK - Scotland	Y	Y	N	N
NICE (2004a)	National Institute for Clinical Excellence	Dental Recall – Recall interval between routine dental examination	UK	N	N	Y	Y
NICE (2004b)	National Institute for Clinical Excellence	Guidance on Cancer Services-Improving outcomes in head and neck cancers (The manual)	UK	Y	N	N	N
CRUK (2005)	Cancer Research UK	Mouth cancer referral guidelines for dentists	UK	N	N	Y	Y
SIGN (2006)	Scottish Intercollegiate Guidelines Network	Diagnosis and management of head and neck cancer	Scotland - UK	Y	Y	Y	Y
AHRQ (2007)	Agency for Healthcare Research and Quality	HealthPartners Dental Group and Clinics oral cancer guideline	US	Y	Y	Y	Y
CCO (2007)	Cancer Care Ontario	Organizational Standards for diagnostic Assessment Programs	Ontario - Canada	N	N	N	N
CDSBC (2008)	College of Dental Surgeons of British Columbia	Guideline for the early detection of oral cancer in British Columbia	British Columbia – Canada	N	Y	N	N

Study	Organisation/ Association	Title of Clinical Guideline	Country	4 themes			
				COE	Adjuncts	Frequency	Target pop.
MOH-NZ (2009)	Ministry of Health New Zealand	Suspected cancer in Primary Care-Guidelines for investigation, referral and reducing ethnic disparities.	New Zealand	N	N	N	N
BDA (2010)	British Dental Association	Early detection and prevention of oral cancer: management strategy for dental practice.	UK	Y	Y	Y	Y
BAO (2011)	British Association of Otorhinolaryngology	Head and neck cancer – multidisciplinary management guidelines.	UK	N	N	N	N
SDCEP (2012)	Scottish Dental Clinical Effectiveness Programme	Oral Health Assessment and Review	Scotland - UK	Y	N	Y	Y
SCCN (2013)	State Cancer Clinical Network. Head and Neck Cancer Working Group	South Australian Head and Neck Cancer Pathway.	South Australia	N	N	Y	Y
NIH (2013)	National Institute of Dental and Craniofacial Research.	Detecting Oral Cancer A guide for Professionals	UK	Y	N	N	Y
USPSTF (2014)	US Preventive Services Task Force.	Screening for oral cancer: US Preventive Services Task Force Recommendation Statement.	US	Y	N	N	Y
MSKCC (2014)	Memorial Sloan Kettering Cancer Center	Head and neck cancer	US	Y	N	Y	Y
SPH (2015)	Solutions for Public Health	Appraisal of Screening for oral cancer	UK	N	Y	N	N

Study	**Organisation/ Association**	**Title of Clinical Guideline**	**Country**	**4 themes**			
				COE	**Adjuncts**	**Frequency**	**Target pop.**
MSCCC (2016)	Maryland State Council on Cancer Control	Maryland comprehensive Cancer control plan - Oral cancer (chapter 12)	Maryland	Y	Y	Y	N
ADA (2017)	American Dental Association	Adjunct for the evaluation of potentially malignant disorders in the oral cavity	US	Y	Y	N	Y

COE = Conventional Oral Examination. Y = Yes, N = No

3.4.5 Methodological Quality of the Sytematic Reviews using AMSTAR Tool

Of the 14 systematic reviews, five were considered low quality (AMSTAR scores 0-4), four were scored as moderate quality (AMSTAR 5-8), and five were judged as having high quality (AMSTAR 9-11). Table 3.3 shows the scores for the individual items and overall AMSTAR scores for each of the included reviews.

Table 3.3 AMSTAR scores for the included systematic reviews (n=14)

	AMSTAR Items*											
Study	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**Total Y**
Gray et al. (2000)	Y	Y	Y	CA	Y	Y	Y	Y	N	N	N	7
Truman et al. (2002)	N	Y	N	N	Y	N	Y	N	CA	N	N	3
Patton. (2003)	N	N	Y	Y	N	Y	N	N	N	N	Y	4
Davenport et al. (2003)	Y	Y	Y	N	Y	Y	Y	CA	Y	CA	N	7
Downer et al. (2004)	N	Y	Y	N	N	Y	CA	N	N	N	Y	5
Downer et al. (2004)	CA	Y	Y	N	N	Y	N	N	Y	N	N	4
Patton et al. (2008)	N	Y	Y	Y	Y	Y	Y	N	N	N	Y	7
Brocklehurst et al. (2010)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	10
Epstein et al. (2012)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	10
Riley et al, (2013)	Y	Y	Y	Y	Y	Y	Y	CA	NA	Y	Y	9
Walsh et al. (2013)	Y	Y	Y	N	Y	Y	Y	Y	Y	N	Y	9
Warnakulasuriya et al. (2014)	N	Y	Y	N	N	Y	N	N	N	N	N	3
Torras et al. (2015)	N	Y	Y	N	N	Y	N	N	N	N	N	3
Lingen et al. (2017)	Y	Y	Y	CA	Y	Y	Y	Y	Y	Y	CA	9

Y = Yes, N = No, CA=Can't Answer, NA = Not Applicable
**The total number of "YES's" is based on final agreement between the reviewers.

3.4.6 Description of the Quality Assessment for the Included Systematic Reviews using AMSTAR Tool

As shown in Table 3.3, 12 included reviews used two independent data extractors, performed a comprehensive literature search and provided the characteristics of their included studies (items 2, 3, 6). Eight reviews assessed the scientific quality of the included studies (item 7), and only four reviews used the results of the methodological rigor and scientific quality in their conclusion (item 8). In terms of combining the findings of studies (item 9) only five reviews used a method to combine the findings properly. The likelihood of publication bias was only assessed in three reviews (item 10). The source of funding was acknowledged in only five reviews (item 11). Around half of the reviews published / provided their protocol (item 1), whereas less than half stated that they searched for reports regardless of their publication type (i.e. grey literature or unpublished literature) (item 4). Eight included reviews provided a list of included and excluded studies (item 5).

3.4.7 Risk of Bias in the Systematic Reviews using the ROBIS Tool

Of the 14 systematic reviews, six were scored as low risk of bias, five were of high risk of bias, and three were considered unclear. Table 3.4 shows the overall scores of the ROBIS tool for each of the 14 included systematic reviews, along with the scores for each of the ROBIS domains.

Table 3.4 ROBIS scores for the included systematic reviews (n=14)

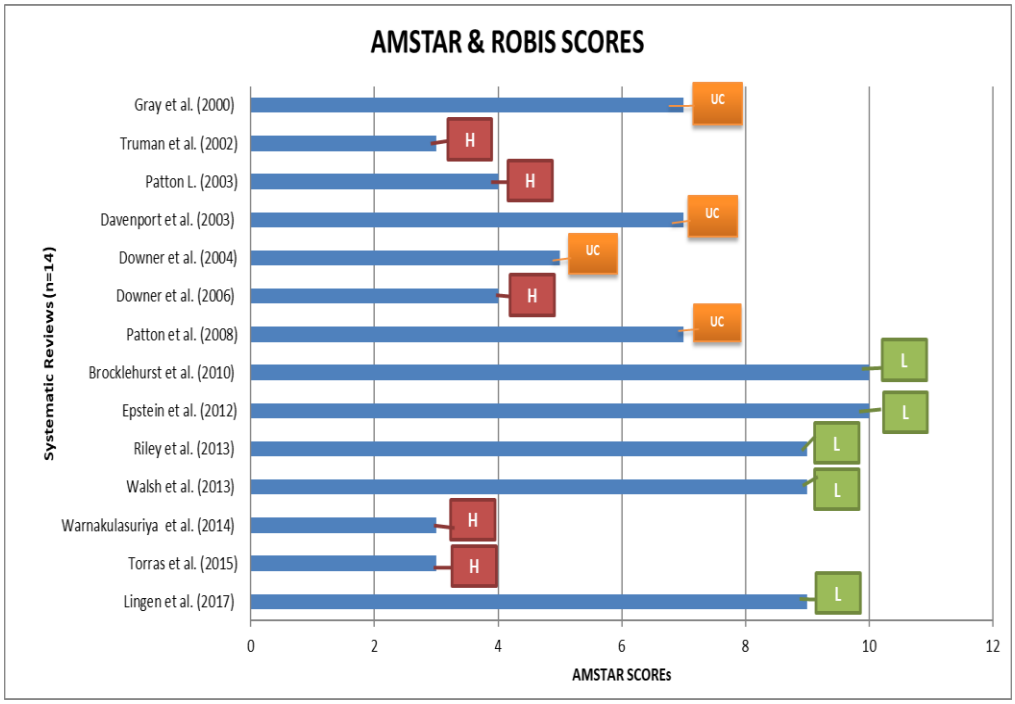
Study (ID)	Judging Risk of Bias				Risk of Bias in the Review*			Risk of Bias Overall
	D1	D2	D3	D4	A	B	C	
Gray et al. (2000)	L	L	UC	H	PN	PY	PY	Unclear
Truman et al. (2002)	H	H	H	H	PN	PN	PN	High
Patton (2003)	H	H	L	H	Y	PY	PY	High
Davenport et al. (2003)	L	L	L	H	PY	PY	PY	Unclear
Downer et al. (2004)	L	L	UC	UC	PY	Y	PN	Unclear
Downer et al. (2006)	L	H	H	H	N	PN	PY	High
Patton et al. (2008)	L	L	L	UC	PN	PY	PN	Unclear
Brocklehurst et al. (2010)	L	L	L	L	Y	Y	PY	Low
Epstein et al. (2012)	H	L	UC	H	PN	PN	N	Low
Riley et al. (2013)	L	L	L	L	PY	PY	PY	Low
Walsh et al. (2013)	L	L	L	L	Y	Y	Y	Low
Warnakulasuriya et al. (2014)	L	L	UC	H	PN	PY	N	High
Torras et al. (2015)	H	L	H	H	PY	PY	N	High
Lingen et al. (2017)	L	L	L	L	Y	Y	PY	Low

D= Domains (i.e. D1=Domain 1, D2= Domain 2, D3=Domain 3, D4=Domain4). (A.B.C=risk of bias sub sections. Y = Yes, PY = Probably Yes, PN = Probably No, N = No, NI = No Information

3.4.8 Comparison of AMSTAR and ROBIS Scores for each Systematic Review

A comparison of AMSTAR and ROBIS scores for each systematic review (n=14) is shown in Figure 3.3. These comparisons were used to provide an overall quality assessment for each systematic review. There were five systematic reviews considered high quality (with high AMSTAR and low ROBIS), four systematic reviews were considered moderate quality (with moderate AMSTAR scores and unclear ROBIS), and five systematic reviews were considered low quality (with consistent low AMSTAR and high ROBIS).

Figure 3.3 AMSTAR and ROBIS scores for the included systematic reviews (n=14)



Lines are AMSTAR scores. Boxes are ROBIS scores – H = High Risk of Bias, L = Low Risk of Bias, UC = Unclear.

3.4.9 Methodological Quality of the Clinical Guidelines

Of the 20 clinical guidelines using the AGREE II tool, six were rated overall as high quality, nine were rated moderate quality, and five rated as low quality. For this review, the overall quality scores of the clinical guidelines ranged from six being the highest score and two the lowest**,** with the mean score being four. There was general agreement between overall score and percentages of domain. There was good alignment between overall score and the scores % of domain #3 – showing that the rigour of methods was driving overall quality.

3.4.9.1 Description of the domains for the clinical guidelines

The AGREE II scores for each clinical guideline in all six domains are shown in Table 3.5. In the scope and purpose domain (Domain 1), the US Preventive Services Taskforce's clinical guideline in screening for oral cancer scored the highest (around 93%) as they clearly defined their overall objectives, the health question and target populations. For the stakeholder involvement domain (Domain 2), both the UK NICE clinical guideline for

recall intervals between routine dental examination, and the US preventive services task force's clinical guideline in screening for oral cancer scored around 85%. Both of these clinical guidelines included patients, their representatives, and other stakeholders in the development of the clinical guidelines. The biggest differences in clinical guidelines were seen in the rigor of development domain (Domain 3), as the highest domain score was 85% for the SIGN guideline, and the lowest was 3% for a private head and neck centre based guideline in USA (Memorial Sloan Kettering Cancer Center). The SIGN guideline in diagnosis and management of head and neck cancer clearly stated the systematic method they used to search for evidence, the selecting criteria of the evidence, the strength and the limitation of the body of evidence, the method they used to formulate the evidence, the health benefits, side effects and risk in formulating the recommendations, the link between the recommendations and the supporting evidence, the experts reviews of their guidelines prior to publication, and they also provide their procedure in updating their guideline. The US Preventive Services Task Force's clinical guideline in screening for oral cancer scored the highest in the clarity of presentation domain (Domain 4). The format of the guideline, the language and the structure were very clear and they scored around (87%) for this domain. Lack of information in relation to potential organisational barriers, cost implications, and tools for application, led to low scores across all clinical guidelines for the applicability domain (Domain 5). The highest score for this domain was 80% and the lowest score was (1%). In general, the score was also low for the clinical guideline's editorial independence domain (Domain 6); which was concerned with the formulation of recommendations not being unduly biased with competing interests. The highest score was 78% for a published review in JADA, and the lowest was 0% for the Memorial Sloan Kettering Cancer Center.

Table 3.5 AGREE II domains score for each clinical guideline

Guideline ID	Domain scores												Overall Quality Score	
	D1		D2		D3		D4		D5		D6			
	Total	%	Total	%	Total	%	Total	%	Total	%	Total	%		
NICE (2004a)	55	85%	55	85%	143	83%	44	65%	59	65%	26	56%	6	High Quality
NICE (2004b)	47	70%	45	67%	114	63%	52	80%	55	60%	22	44%	6	
SIGN (2006)	47	70%	46	69%	147	85%	53	81%	58	64%	34	78%	6	
MOH-NZ (2009)	53	81%	51	78%	122	68%	52	80%	37	35%	32	72%	6	
USPSTF (2014)	59	93%	55	85%	140	81%	56	87%	43	43%	33	75%	6	
ADA (2017)	54	83%	41	59%	118	65%	53	81%	37	35%	32	72%	6	
SDCEP (2012)	49	74%	50	76%	98	51%	45	67%	59	65%	25	53%	5	Moderate Quality
SCCN (2013)	49	74%	35	48%	122	68%	44	65%	43	43%	28	61%	5	
AHRQ (2007)	41	59%	35	48%	121	67%	23	26%	28	22%	27	58%	4	
BAO (2011)	41	59%	38	54%	79	38%	54	83%	25	18%	8	6%	4	
SPH (2015)	48	72%	32	43%	120	67%	47	70%	18	8%	9	8%	4	
CCO (2007)	52	80%	27	33%	91	47%	35	48%	43	43%	9	8%	3	
CDSBC (2008)	50	76%	42	61%	42	13%	44	65%	25	80%	14	22%	3	
BDA (2010)	46	69%	31	41%	69	31%	48	72%	54	58%	14	22%	3	
MSCCC (2016)	22	24%	23	26%	51	19%	33	44%	37	35%	11	14%	3	
ACS (2003)	30	39%	20	20%	43	13%	30	39%	13	1%	14	22%	2	Low Quality

Guideline ID	Domain scores												Overall Quality Score	
	D1		D2		D3		D4		D5		D6			
	Total	%	Total	%	Total	%	Total	%	Total	%	Total	%		
GU-GDS (2003)	34	46%	13	7%	26	1%	26	31%	21	13%	17	31%	2	Low Quality cont.
CRUK (2005)	37	52%	28	35%	33	6%	51	78%	18	8%	14	22%	2	
NIH (2013)	25	30%	17	15%	42	13%	44	65%	18	8%	11	14%	2	
MSKCC (2013)	25	30%	17	15%	29	3%	39	56%	20	11%	6	0%	2	

3.5 Data Synthesis

3.5.1 Domain Identification

Data from the included systematic reviews and clinical guidelines were extracted for the four themes. Table 3.6 shows the themes covered in each of the systematic reviews grouped by study quality; and Table 3.7 indicates the themes included in each of the clinical guidelines grouped by guideline quality.

Table 3.6 Summary of themes covered in systematic review and overall quality rating

Quality Level	Study Code	4 themes			
		Conventional Oral Examination	Use of adjunct	Target population	Frequency of assessment
High	Epstein et al. (2012)	Y	Y	Y	N
	Brocklehurst et al.(2013)	Y	Y	N	N
	Riley et al. (2013)	N	N	N	Y
	Walsh et al. (2013)	Y	Y	Y	N
	Lingen et al. (2017)	N	Y	N	N
Moderate	Gray et all. (2000)	N	Y	N	N
	Davenport et al. (2003)	N	N	N	Y
	Downer et al. (2004)	Y	Y	N	N
	Patton et al. (2008)	N	Y	N	N
Low	Truman et al. (2002)	N	N	N	N
	Patton. (2003)	Y	Y	Y	N
	Downer et al. (2006)	N	N	Y	N
	Warnakulasuriya et al. (2015)	Y	N	Y	N
	Carreras-Torras & Gay-Escoda. (2015)	Y	Y	Y	Y

Y = Yes, N = No

Table 3.7 Summary of themes covered in Clinical Guidelines with overall quality rating

Quality Level	CG ID	Organisation/association	Country	4 themes			
				COE	Use of Adjunct	Frequency	Target pop
High	NICE (2004a)	National Institute for Clinical Excellence	UK	N	N	Y	Y
	NICE (2004b)	National Institute for Clinical Excellence	UK	Y	N	N	N
	SIGN (2006)	Scottish Intercollegiate Guidelines Network	Scotland - UK	Y	Y	Y	N
	MOH-NZ (2009)	Ministry of Health New Zealand	New Zealand	N	N	N	N
	USPSTF (2014)	US Preventive Services Task Force.	US	Y	N	N	Y
	ADA (2017)	American Dental Association	US	Y	Y	N	Y
Moderate	AHRQ (2007)	Agency for Healthcare Research and Quality	US	Y	Y	Y	N
	CCO (2007)	Cancer Care Ontario	Ontario - Canada	N	N	N	N
	CDSBC (2008)	College of Dental Surgeons of British Columbia	British Columbia - Canada	N	Y	Y	Y
	BDA (2010)	British Dental Association	UK	Y	Y	Y	Y
	MSCCC (2011)	Maryland State Council on Cancer Control	Maryland	Y	Y	Y	N
	BAO (2011)	British Association of Otorhinolaryngology	UK	N	N	N	N
	SDSEP (2012)	Scottish Dental Clinical Effectiveness Programme	Scotland - UK	Y	N	Y	Y
	SCCN (2013)	State Cancer Clinical Network. Head & Neck Cancer Working Group	South Australia	N	N	Y	N
	SPH (2015)	Solutions for Public Health	UK	N	Y	N	Y

Quality Level	CG ID	Organisation/association	Country	COE	Use of Adjunct	Frequency	Target pop
Low	ACS (2003)	American Cancer Society	USA	Y	N	Y	Y
	GU-GDS (2003)	University of Glasgow-Glasgow Dental School	UK - Scotland	Y	Y	N	N
	CRUK (2005)	Cancer Research UK	UK	N	N	Y	Y
	NIDCR (2013)	National Institute of Dental and Craniofacial Research.	UK	Y	N	N	N
	MSKCC (2014)	Memorial Sloan Kettering Cancer Center	US	Y	N	Y	Y

3.5.2 Theme One – Conventional Oral Examination (COE)

This theme focuses on the clinician's role in the primary health care dental setting in performing conventional clinical visual and tactile intra- and extra-oral examinations on their dental patients. This theme assesses the evidence in relation to conducting such examinations as part of their routine care in terms of its effectiveness in detecting oral potentially malignant disorders (lesions) or in detecting oral cavity cancer at an early stage.

The effectiveness of screening tests is assessed by the measures: sensitivity and specificity (IARC, 1999). Sensitivity measures the ability of a screening test to correctly identify those with a disease (or true positive rate). Specificity measures the ability of a screening test to correctly identify those without the disease (true negative rate). Thus sensitivity measures true positive tests, while specificity measures false negatives.

3.5.2.1 Systematic review

High quality systematic reviews

Three of the five systematic reviews rated as high quality considered the conventional oral examination (COE), with two focusing on sensitivity and specificity (Table 3.8). Walsh et al (2013) in their high quality Cochrane systematic review undertook an analysis of

sensitivity and specificity of 10 studies (with 25,568 participants) which evaluated the COE against a gold standard expert specialist clinical examination. There was a wide range of types of screening studies evaluated in the review, including: opportunistic screening (e.g. as part of a routine check-up appointment by a dentist) or as part of an organised population-based screening programme. While there was limited difference by these study types, the review found that the sensitivity estimates were highly variable and dependent on the prevalence of oral cavity cancer (OCC) or OPMD (which itself varied from 1 to 51% in the studies analysed). In the eight studies with prevalence of 10% or lower, the sensitivity estimates were highly variable - ranging from 50% to 99%, while specificity was consistently high around 98%. Where the prevalence, in one study, was higher (22%), sensitivity was 95% and specificity was 81%; and in another where prevalence was higher still (51%), the sensitivity was 97% and specificity was 75%.

Thus, in low prevalence populations (typically between 1 and 5%), the COE was consistently better at classifying the absence of OPMD or OCC in disease free individuals than the more variable performance in classifying the presence of disease in individuals with OPMD or oral cavity cancer.

The Walsh et al (2013) Cochrane review complements another recent robust high-quality Cochrane review by Brocklehurst and colleagues (2013), which assessed the overall effectiveness of screening programmes for the early detection and prevention of oral cancer. It identified only one randomised control trial of a conventional oral examination which was followed up for a sufficiently long enough period to assess mortality outcomes. The RCT was undertaken in Kerala, India with COEs performed by trained health workers and they followed participants up for 15 years. The study reported a relatively lower sensitivity (than Walsh et al 2013) of 64% but did not report specificity, and Brocklehurst et al (2013) in their review undertook a post-hoc analysis of positive predictive test performance of 74% (calculated based on the number of screen-selected oral cancers as a proportion of total screen positive biopsy confirmed subjects). While the evidence in the systematic review was limited to one trial (which was also assessed as having some risk of bias), the review authors concluded that opportunistic screening via COE – particularly in high risk individuals (identified as those who used tobacco or alcohol or both) – may potentially improve outcomes through detecting cancer at an earlier stage.

Epstein et al (2012) assessed the effectiveness of COE in predicting histologic diagnosis of dysplasia or OCC. They found poor correlation between the diagnosis made on the basis of

COEs and the diagnosis made on the basis of biopsy results. The review reported 93% sensitivity for COE, but specificity was only 31%. They concluded that COE alone was not enough to detect OPMD and OCC.

Overall, the high quality systematic reviews identified some, albeit limited, evidence of the effectiveness of COE in the detection of OPMD and OCC – with a tendency for increasing sensitivity with increasing prevalence populations, and a suggestion via a single RCT of increased COE effectiveness (in terms of improved survival outcomes) among higher risk individuals.

Table 3.8 High Quality Systematic Review- COE

Study ID	Results and / or Conclusions
Walsh et al (2013)	Prevalence OCC or OPMD <10% Sensitivity = 0.50 (95%CI 0.07, 0.93) to 0.75 (95% CI 0.92, 0.97) Specificity = 0.98 (95%CI 0.97, 1.00) Prevalence OCC or OPMD = 22% Sensitivity = 0.95 (95%CI 0.92, 0.97) Specificity = 0.81 (95%CI 0.79, 0.83) Prevalence OCC or OPMD = 51% Sensitivity = 0.97 (95%CI 0.96, 0.98) Specificity = 0.75 (95%CI 0.73, 0.77) "Index tests at a prevalence reported in the population (between 1% and 5%) were better at correctly classifying the absence of OPMD or oral cavity cancer in disease-free individuals than classifying the presence in diseased individuals". "General dental practitioners and dental care professionals should remain vigilant for signs of OPMD and oral cancer whilst performing routine oral examinations in practice".
Brocklehurst et al (2013)	Only one RCT included (assessed as having a high risk of bias). Sensitivity of 64% but did not report specificity. Post-hoc analysis of positive predictive test performance of 74%. Comparing screened group and control group Overall mortality RR = 0.88 (95%CI 0.69, 1.12) High-risk individuals (tobacco and/or alcohol) RR = 0.76 (95%CI 0.60, 0.97) No differences in incidence rates Reduction in Stage III or worse RR = 0.81 (95%CI 0.70, 0.93) "…opportunistic visual screening by appropriately trained dentists and oral

Study ID	Results and / or Conclusions
	health practitioners is recommended for all patients and particularly for those who use tobacco, alcohol or both. Systematic examination of the oral cavity by front-line health workers should remain an integral part of their routine for routine recall appointments".
Epstein et al (2012)	Diagnostic OR = 6.1 (95%CI 2.1, 17.6) Sensitivity = 0.93 (95%CI 0.91, 0.94) Specificity = 0.31 (95%CI 0.28, 0.34) "COE was considered to have poor overall performance as a diagnostic method for predicting dysplasia and OSCC". "COE of mucosal lesions generally is not predictive of their histologic diagnosis".

Moderate quality systematic reviews

Only one review rated as having moderate quality and moderate risk of bias assessed COE (Appendix 3.10). The earlier systematic review (Downer et al., 2004), included a meta-analysis of eight studies (prospective cohorts with gold standard verification) with wide variation in prevalence of OPMD / OCC lesions (from 2% to 51%). They reported a weighted pooled estimate of sensitivity (85%) and estimate of specificity (96%) for COE. These relatively high levels led to the authors more assertively positive conclusion for COE: "A generally high level of discriminatory ability and consistency in test performance was apparent among the studies included, irrespective of their clinical heterogeneity".

The addition of this moderate quality systematic review would provide more (confirmatory) support for the role of COE.

Low quality systematic reviews

Of the five lower quality systematic reviews, four considered the effectiveness of COE (Appendix 3.11). The most recent review by Warnakulasuriya and colleagues (2015) identified a larger number (n=16) of studies (all from Europe) and wider range of study types (not limited to RCTs) than the other reviews. They examined the effectiveness of COE and reported that there were no consistent results in the studies reviewed and that only a small number of studies (n=6) analysed against histological confirmed outcomes. No meta-analysis of these studies was undertaken, only ranges of sensitivity (0.68 – 0.98) and specificity (0.71 – 0.96) for COE were reported. The review authors strongly concluded that the feasibility of screening for OPMDs by COE was demonstrated, however, they recognised the need for more testing and research of implementation strategies in European countries.

Carreras-Torras and Gay-Escoda (2015) included a brief description of current protocols for detecting OPMD via a COE – this involved visual inspection of the oral cavity and tactile examination of the head and neck lymph nodes. Their (lower quality) review concluded that COE alone cannot reliably differentiate between benign and dysplastic lesions due to its low specificity and high sensitivity (quoting Epstein et al 2012 data), and that this was mainly because many of the benign lesions look like oral malignancies.

Evidence was also lacking in the earlier and quite limited systematic review that was conducted by Patton (2003) in relation to the effectiveness of visual screening in community settings. The author stated that with low population prevalence, the actual value of screening in detecting new cases of OCC is more effective in high risk individuals than mass population screening.

3.5.2.2 Clinical Guidelines

High quality clinical guidelines

Of the six clinical guidelines rated as high quality, four reported evidence-based recommendations in relation to the clinical oral examination. These guidelines were: NICE (2004b), SIGN (2006), USPSTF (2014), and ADA (2017).

The scope of review of the USPSTF (2014) included the role of oral cancer screening by means of clinical visual inspection and palpation performed by the primary care providers on asymptomatic adults as a means of reducing associated morbidity and mortality. The terms "asymptomatic" is not clearly defined in the document, however, it is implied that it is the general routine adult population attending primary care providers. They conclude: "… the USPSTF is unable to make a recommendation in favour of or against screening." (rated as "I" (insufficient) evidence statement). This guideline concludes that there is: "… inadequate evidence that the oral screening examination accurately detects oral cancer."; that there is "…. inadequate evidence on the diagnostic accuracy [of COE]"; and that there is "… inadequate evidence… [COE] … improves morbidity or mortality" (rated as "I" (insufficient) evidence. (Table 3.9). USPSTF (2014) described the COE "screening test" as involving visual inspection (with the aid of a mouth mirror) of the face, neck, lips, labial mucosa, and buccal mucosa, and gingiva, floor of the mouth, tongue, and palate; as well as tactile palpation of the regional lymph nodes of the neck, tongue, and floor of the mouth. The guideline also assessed the evidence in relation to the accuracy of screening in

identifying oral cancer or OPMD. This high quality clinical guideline reported that there was insufficient evidence on whether screening reduces morbidity or mortality in general or in high risk US populations. It also stated that there was a lack of evidence on harms from the screening test or from false positive or false negative results. The USPSTF (2014) referenced the NIDCR (2013) guideline in making the recommendations, which is a simple guide for health care professionals on how to perform COE for oral cancer or OPMD.

The ADA (2017) guidelines updated the ADA (2010) clinical guideline and made evidence-based recommendations for primary care practitioners in relation to the assessment and detection of oral cancer. The ADA (2017) guideline has a particular focus on the role of adjuncts for the evaluation of OPMDs (and undertakes its own systematic review as part of the process (Lingen et al, 2017). This high-quality evidence-based document recommended: "The panel suggests that clinicians [dentists] should obtain an updated medical, social, and dental history and perform an intraoral and extraoral conventional visual and tactile examination [refers to initial, routine, or emergency visits] in all adult patients" (rated as Good Practice Statement – based on no quality of evidence rating, and no strength of recommendation assigned). This review does not reference or cite the Kerala RCT (Sankaranarayanan et al, 2005) as reviewed in ADA (2010), where they concluded that community-based screening by means of visual and tactile examination in the general population intended to detect early and advanced oral cancer may not alter disease specific mortality, but may reduce oral cancer mortality among the high risk group (defined as smokers and alcohol drinkers). ADA (2010) also rated the evidence in this area as a "Good Practice Statement" – which they define as based on an "overwhelming amount of indirect evidence" (Table 3.9). The indirect evidence includes drawing heavily on the Kerala RCT (Sankaranarayanan et al, 2005) and an earlier Cochrane systematic review by Kujan et al. (2006).

Similarly, the SIGN (2006) guideline on diagnosis and management of head and neck cancer stated that: "Dental practitioners should include a full examination of the oral mucosa as part of routine dental check-ups" (rated as a "Good Practice Point" – i.e. based on clinical guideline development group expert opinion, which was below the four grades of recommendation used in this guideline; Table 3.9). Moreover, SIGN (2006) did not specify or detail the steps involved in the clinical oral examination process.

NICE (2004b) is guidance for cancer services to improve outcomes in head and neck cancer. While this guidance document focused on developing urgent referral guidance and

referral pathways for patients with suspected head and neck cancer, it does, however, make the point that "… systematic examination of the oral mucosa by dentists could be carried out as part of routine dental inspection" (rated as "Grade B" – i.e. mid-level evidence in their guideline; Table 3.9).

Table 3.9 High Quality Clinical Guidelines – COE

CG -ID	Year	Recommendations	Evidence Rating
NICE (2004b)	2004	"… systematic examination of the oral mucosa by dentists could be carried out as part of routine dental inspection."	Grade B – Base on evidence from non-randomised control trials or observational studies
SIGN	2006	"Dental practitioners should include a full examination of the oral mucosa as part of routine dental check-up [sic]."	Good Practice Point – Based on the clinical experience of the guideline development group.
USPSTF	2014	"… inadequate evidence that the oral screening examination accurately detects oral cancer." "… inadequate evidence on the diagnostic accuracy [of COE]". "… inadequate evidence … [COE] … improves morbidity or mortality."	I statement – Based on conclusion that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.
ADA	2017	"The panel suggests that clinicians [dentists] should obtain an updated medical, social, and dental history and perform an intraoral and extraoral conventional visual and tactile examination [refers to initial, routine, or emergency visits] in all adult patients."	Good Practice Statement – Based on no quality of evidence rating, with no strength of recommendation assigned

All of these high quality clinical guidelines suggest that any abnormality detected should be re-evaluated in two weeks and if still present biopsied or referred for biopsy. The (higher quality) clinical guidelines acknowledge that there is limited evidence on the effectiveness of a clinical visual and tactile examination in detecting both oral cancer (including at an earlier stage) and OPMD in asymptomatic adults in primary dental care. However, largely on the basis of expert opinion, these guidelines recommend that a full mouth examination should be an integral part of routine dental examinations (check-ups)

and that clinicians should stay alert for signs and symptoms and use their clinical judgment and experience. Moreover, these high quality clinical guidelines did not detail or specify the processes involved in the clinical visual and tactile examination – which is perhaps not surprising given a limited evidence base on these specific aspects to draw from. Furthermore, the grading schemes, which were used in these clinical guidelines, concluded that the evidence was not at a sufficiently high level, i.e. the grades were based on: insufficient evidence; evidence from one RCT only; evidence from non-experimental descriptive studies; or from the expert clinical experience of the guidelines development team.

Moderate quality clinical guidelines

The nine moderate (and indeed the low) quality clinical guidelines, in contrast to the high quality ones, provided more in-depth recommendations and descriptions in relation to how to perform the clinical oral examination. These recommendations were based on expert opinion rather than cited evidence (Appendix 3.12).

The MSCCC (2016) cited the ADA (2010) and "recommends that dentists look for signs of cancer while performing routine exams in all patients, particularly those who use tobacco or consume alcohol heavily" and the ACS (2003) "recommends oral exams as part of routine cancer-related check-ups". The MSCCC (2016) was an update of MSCCC (2011) which performed a review of existing US clinical guidance at the time, which came to same conclusions.

The South Australian SCCN (2013) guidelines recommended "…dental and medical examinations with appropriate health questionnaires (such as skin, voice, oral symptoms, swallowing and behavioural assessments for risk factors)". There was no evidence base cited, nor was the strength of recommendation given.

The older US AHRQ (2007) guideline described as a "major recommendation" that "visual examination of the oral soft tissues, extraoral head and neck tissues and palpation of the head and neck lymph nodes is considered the standard of care as part of a complete dental examination". It did not describe the strength of the recommendation or evidence base.

The SDCEP (2012) clinical guidelines provided details for the dental team on conducting a comprehensive oral health assessment. It provided action points (recommendations) for the dental team at a summary level within their Guidance in Brief document and more detailed

level guidance in the full document. The action points were not given a strength of recommendation nor was the evidence base cited.

The BDA (2010) clinical guidelines "occasional paper" on early detection and prevention of oral cancer similarly did not cite the evidence base or assign a strength of recommendation. It recommended a "head and neck and oral soft tissue examination should be carried out…" – they provided a detailed guide on visual and tactile examination (data not shown).

The UKSPH (2015), made reference to the Walsh et al (2013) systematic review, and reported that there was insufficient evidence to determine the accuracy of a COE. This guideline also found one study (Ibrahim et al, 2014) published since Walsh et al (2013) which claimed 100% sensitivity for COE, however, the study design was weak with no follow-up and it could not reliably ascertain cases of oral cancer that were missed by screening.

Low quality clinical guidelines

Of the five clinical guidelines rated as low quality, three made recommendations in relation to COE (Appendix 3.13). One low quality clinical guideline from the US National Institute of Dental and Craniofacial Research (NIDCR, 2013) provided a detailed procedure for health care professionals on how to conduct the intra-oral and extra-oral examination. This was produced in the form of a leaflet / poster to act as an accessible guide for health care professionals. Although there was no evidence that any specific screening / examination method could have improved outcomes for those diagnosed with head and neck cancer. The other lower quality clinical guideline by the Memorial Sloan Kettering Cancer Center in US (MSKCC, 2014) recommended a head and neck examination including the oral cavity and oropharynx by a primary care physician. However, it did not provide any details on how these examinations should be performed. The University of Glasgow – Glasgow Dental School (GU-GDS) clinical guidelines recommended a thorough and methodological examination of the mouth. A detailed step-by-step guide for undertaking extra-oral and intra-oral examination for suspicious lesions was provided. The GU-GDS clinical guideline also did not make reference to the evidence base.

3.5.3 Theme Two: Target Population

This theme aims to assess the evidence in relation to the "target population" for receiving early detection / screening of oral cavity cancer or OPMD interventions. It will address questions including: should they be delivered via a mass or invitational screening approach for the general population, or an opportunistic approach for those attending primary health care settings?; and should they be delivered to all patients attending these settings, or further targeted to high risk individuals (i.e. tobacco / alcohol users)?

3.5.3.1 Systematic Reviews

High quality systematic reviews

The Cochrane review by Walsh *et al*., (2013) covered the issue of the target population for COE for early detection / screening of oral cavity cancer or OPMD; however, it was not a primary focus of their review. Out of the thirteen studies appraised in their review, five included "high risk" groups which were defined as either having a previous history of head and neck cancer or were older tobacco smokers. These studies were generally undertaken in high prevalence countries and reported higher sensitivity and specificity of the COE to detect OPMD (as in Table 3.10). The authors reported that although the evidence of the accuracy of the COE for early detection of OPMD was not consistently strong, there was some evidence that COE as a component of a population screening programme could reduce mortality and produce stage-shift in high risk populations (Kerala study). However, they concluded that "General dental practitioners and dental care professionals should remain vigilant for signs of OPMD and oral cancer whilst performing routine oral examinations in practice."

The Cochrane systematic review by Brocklehurst *et al.*, (2013) found evidence for a population-based screening programme reducing the mortality rate in high risk individuals (defined as tobacco smokers and alcohol drinkers) rather than in a high risk population per se (Table 3.10). This finding was from the community-based randomised controlled trial of oral cancer screening from Kerala in India (Sankaranarayanan et al., 2005). The review points out that while the study was conducted in a relatively high prevalence population base, the effectiveness in terms of stage shift of earlier detection and reduced mortality was observed in high risk individuals (those who smoked tobacco and drank alcohol). However, they do report concerns about the fact it was only one trial and that the trial had

a high risk of bias. The review also examined the health economic literature (including economic evaluation of the Kerala study), reporting that COE could be cost-effective among high risk individuals – with improved survival and reduced treatment burden associated with earlier stage shift of detection. However, this was a post-hoc extrapolation from data from a population-wide community screening programme. They reported that COE was effective, and also cost effective when focused on high risk individuals – with improved survival, and reduced treatment burden associated with stage-shift.The Brocklehurst et al. (2013) review, as per the Walsh et al. (2013) review, concluded that "opportunistic visual screening by appropriately trained dentists and oral health practitioners is recommended for all patients and particularly for those who use tobacco, alcohol or both."

Table 3.10 High Quality Systematic Review (Target Population)

Study ID	Results and / or Conclusions
Walsh et al (2013)	"... even though the evidence of accuracy is not consistently strong, there is some evidence ... that implementing COE as a component of a population screening programme can reduce mortality and produce stage-shift in a high-risk population." "General dental practitioners and dental care professionals should remain vigilant for signs of OPMD and oral cancer whilst performing routine oral examinations in practice."
Brocklehurst et al (2013)	"There is evidence that a visual examination as part of a population-based screening programme reduces the mortality rate of oral cancer in high-risk individuals." "However, the evidence is limited to one study, which has a high risk of bias and did not account for the effect of cluster randomisation in the analysis." "... good evidence that opportunistic screening of high-risk groups is cost-effective" ... "However, these results also need to be read in context of the relative prevalence of the condition." "The results suggest that there is insufficient evidence to recommend a whole population screening programme for oral cancer. However, the results from the Kerala study suggest that a targeted population approach could reduce the mortality rate and produce a stage shift, but the risk of bias in the included study means that further well-designed randomised controlled trials are necessary to establish the validity of this relationship." "In the meantime, opportunistic visual screening by appropriately trained dentists and oral health practitioners is recommended for all patients and particularly for those who use tobacco, alcohol or both. Systematic examination of the oral cavity by front-line health workers should remain an integral part of their routine for routine recall appointments."

These two high quality systematic reviews drawing on largely the same original studies agreed: i) that a conventional oral examination should be performed opportunistically as part of routine dental care – although this statement lacked an evidence-base itself and was more precautionary; ii) that there was insufficient evidence for population / invitational screening approaches; and iii) despite some evidence in support of greater effectiveness in high risk individuals, they both considered it insufficient to recommend an approach which focused on or stratified to high risk individuals, favouring an opportunistic approach on all patients attending dental practice.

Moderate quality systematic reviews

The moderate quality systematic reviews did not specify any details about the target population in relation to early detection / screening for oral cavity cancer or OPMD.

Low quality systematic reviews

The Warnakulasuriya et al. (2015) systematic review included 16 European studies (no randomised controlled trials) assessing COE to detect OCC or OPMD. While they did not synthesise the study findings, they found no evidence to support either a population-based or targeted screening approach, with some mixed evidence on invitational approaches (which seemed to be more successful in workplace settings). They concluded by proposing that the two possible best approaches, which would need further research on effectiveness, would be opportunistic screening in dental practices or screening of selected high-risk populations (Appendix 3.14). Warnakulasuriya et al (2015) also noted the concerns that a dental practice approach would not include sufficient high-risk individuals (as they are less likely to attend dental settings) – which has previously been described as the “inverse screening law” (Netuveli et al., 2006).

The earlier systematic review by Patton (2003) reported insufficient evidence to draw conclusions regarding the effectiveness of COE for oral cancer screening in community settings in low risk populations, but reported (without particular reference to evidence) that targeted COE of high-risk individuals may be more effective than mass screening. Patton also recommended that: i) adults above the age of 40 should undergo regular routine COE as part of medical and dental primary health care check-ups; ii) high risk groups (tobacco and alcohol users) should be motivated to regularly attend primary care settings for COE;

and iii) tobacco cessation interventions could be included as part of the early detection / screening COE intervention (Appendix 3.14).

A systematic review by Downer *et al.*, (2006), also produced no evidence on potential benefits associated with an oral cancer screening programme. Upon review completion they reported in their discussion that evidence had emerged from the report of the Kerala study, which stated that screening for OCC "may be effective; at least in developing countries with a high incidence of the disease".

These lower quality-rated systematic reviews similarly supported opportunistic early detection / screening approaches, but more clearly identified that high risk individuals were less likely to attend routine dental appointments for this opportunity and therefore some form of targeted encouragement to reach these groups was needed.

3.5.3.2 Clinical Guidelines

High quality clinical guidelines

Three of the six high quality-rated clinical guidelines included details of the target population for early detection / screening (National Institute for Clinical Excellence, 2004; USPSTF, 2014; ADA, 2017)

The NICE (2004a) dental recall clinical guideline recommended that: a "thorough dental, head and neck examination" should be carried for "all new NHS dental patients" and for all returning patients attending for "check-up" appointments; and a social history for excessive alcohol and tobacco use should be undertaken each time. The outcome of the social history did not influence whether the patient should have a COE or not or the nature / content of the COE (Table 3.11). These recommendations were evidence-graded as "GPP – A good practice point is a recommendation for best practice based on the clinical experience of the Guideline Development Group".

The USPSTF (2014) guidelines did not recommend population based screening – this was given a "Grade I statement", as mentioned above in the first theme (COE). The supplementary evidence synthesis found that there was no evidence on oral cancer screening either for the general population or for selected high-risk groups which would be applicable to the US. However, they noted that high-risk group targeted screening strategies may be applicable in high prevalence populations (this was based on the one "Kerala RCT" which they rated as having "good quality"). This guideline also reviewed

the health economic literature. Here they reported that a targeted (high-risk) approach in primary care dental (and perhaps medical) settings was potentially cost-effective (this was based on one RCT, and two decision-analysis models).

The ADA (2017) clinical guidelines recommended that dental clinicians undertake COE in all adult patients after updating their medical, social, and dental history (no quality of evidence rating, nor strength of recommendation was assigned). This high quality-rated clinical guideline supports opportunistic COE for all patients attending dental appointments.

Table 3.11 High Quality Clinical Guidelines (Target Population)

CG -ID	Year	Recommendations	Evidence Rating
NICE	2004b	"New NHS dental patient: Full patient histories recorded; Thorough dental, head and neck examinations for new NHS dental patient" "Oral Health Reviews: Update patient histories, Update exam."	GPP – A good practice point is a recommendation for best practice based on the clinical experience of the Guideline Development Group
USPSTF	2014	"... concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for oral cancer in asymptomatic adults."	I statement – Based on conclusion that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.
ADA	2017	"The panel suggests that clinicians [dentists] should obtain an updated medical, social, and dental history and perform an intraoral and extraoral conventional visual and tactile examination [refers to initial, routine, or emergency visits] in all adult patients."	Good Practice Statement – Based on no quality of evidence rating, with no strength of recommendation assigned

Moderate quality clinical guidelines

The target population for early detection / screening was covered in five of the nine clinical guidelines rated as moderate quality: (CDSBC, 2008; BDA, 2010; SDCEP, 2012; UKSPH, 2015; MCCCP, 2016) (Appendix 3.15).

The UKSPH (2015) considered the UK National Screening Committee criteria (UKNSC) in relation to the effectiveness of a COE in either a population or targeted basis were not met. This assessment was based largely on the Walsh et al (2013) Cochrane review.

The Maryland Comprehensive Cancer Control Plan - MCCCP (2016) guidelines reviewed four other earlier North American clinical guidelines, which had been published between 1996 and 2003, only one of which (ACS 2003) was included in this overview. They identified a lack of consensus in relation to target population and opportunistic vs. population approaches. They concluded that there was insufficient evidence to recommend general population screening. However, for high risk or indeed for opportunistic screening of all patients they noted that "this does not mean that such examinations are not effective". They also pointed out that those at highest risk may be less likely to attend for regular dental appointments and that screening efforts should also focus on encouraging medical physicians to routinely inspect the oral cavity in high risk patients; and they went on to recommend extending opportunities for opportunistic screening (Appendix 3.15).

The SDCEP (2012) clinical guidance on oral health assessment recommended that a COE was performed on all patients (irrespective of risk) attending primary care dental practice. This was based solely on the "expert opinion of the guideline development group".

The British Dental Association (BDA, 2010) recommended that a head and neck and oral soft tissue examination be carried out on all patients as part of their routine dental "check-up" appointments. They proposed that this examination should occur at the start of each new course of treatment, and further / more frequent check-ups need to be undertaken for high risk groups (smokers and alcohol users). There was no reference to the evidence base for these recommendations. They also did not find evidence to support population-based screening, but recommended opportunistic screening (COE) in dental settings for all patients. However, the recommendations were based on a UK report on screening for cancer and precancer which was published in 1993 (Appendix 3.15).

The College of Dental Surgeons of British Columbia (CDSBC- 2008) recommended COE on “all patients at the time of the new patient examination and at the general dental recall [appointment]”. It was not clear what evidence this was based on.

Taken together, the moderate quality-rated clinical guidelines did not differ from the higher quality clinical guidelines – generally recommending COE opportunistically for all patients attending primary dental care appointments, based on expert opinion rather than an evidence-base.

Low quality clinical guidelines

The four low quality clinical guidelines which considered the target population for early detection / screening of oral cancer were: (ACS, 2003; CRUK, 2005; NIH, 2013; MSKCC, 2014; Appendix 3.16).

MSKCC (2014) advised that all individuals visit a primary care physician for a COE and visit a dentist for “dental evaluation”, although they acknowledge that “no screening method has been proven to improve survival for people with head and neck cancer”. No evidence sources were quoted.

NIDCR (2013) stated that the COE should be undertaken during the dental check-up visit. It went on to say “clinicians should be particularly vigilant in checking those who use tobacco or excessive amounts of alcohol”. There were no details provided on how to be particularly vigilant or whether that would involve doing anything differently. There was no evidence source provided for this statement.

CRUK (2005) and ACS (2003) were similar in proposing some targeting based on age-group and risk factors. While CRUK recommended COE in every dental examination, they suggested this should be undertaken with a “higher level of suspicion” and “if the patient is a smoker or heavy alcohol drinker, chews betel nut (areca nut) or tobacco, or is over 40 years”, although there were no details of what undertaking a COE with a “higher level of suspicion” would involve. ACS (2003) recommended COE on the occasion of a periodic health examination, rather than a stand-alone examination for those aged 20 years and over.

These low quality-rated clinical guidelines also generally recommended opportunistic COE as part of regular dental and health check-ups.

3.5.4 Theme Three: Frequency of Conventional Oral Examination

The frequency of people having a Conventional Oral Examination in primary care dental practice is intertwined with the frequency of dental "check-ups" (which should include both a dental and oral health assessment). How the recall interval between such visits is determined is increasingly subject to review in many countries. Traditionally this recall interval has been fixed at six-monthly for all (Riley et al., 2013). However, the justification and lack of evidence base for this has been questioned (Davenport et al., 2003). Integral to determining the frequency of a COE is the risk associated with oral cancer or OPMD.

3.5.4.1 Systematic Reviews

Very few systematic reviews have specifically considered the issue of the frequency of COE for early detection / screening for OCC or OPMD.

High quality systematic reviews

One high quality-rated systematic review by Riley et al. (2013) aimed to determine the beneficial and harmful effects of different fixed recall intervals (e.g. 6 months versus 12 months) for dental check-ups. This Cochrane review took oral cancer into its consideration, but identified only one small RCT with 188 participants, which the reviewers assessed as having a high risk of bias (Table 3.12). Therefore, no conclusions were made regarding the beneficial and harmful effect of varying recall intervals between dental checks.

Table 3.12 High Quality Systematic Review - Frequency

Study ID	Results and / or Conclusions
Riley et al (2013)	"There is a very low-quality body of evidence from one RCT which is insufficient to draw any conclusions regarding the potential beneficial and harmful effects of altering the recall interval between dental check-ups."

Moderate quality systematic reviews

The clinical effectiveness and cost effectiveness of routine dental checks was assessed by (Davenport et al., 2003). This moderate quality review also assessed the cost effectiveness of routine dental checks of different recall frequencies in improving quality of life,

reducing the morbidity associated with dental caries, periodontal disease, and oral cancer, as well as reducing the mortality associated with oral cancer in adults. In the review, two studies (one cross-sectional and one retrospective case-series) were included that investigated the relationship between frequency of dental check-ups and oral cancer outcomes. These two studies both from the 1990s had conflicting results. The cross-sectional study based in primary and secondary care settings in London, UK (involving n= 2027 participants) found that recall intervals of less than 12 months do not impact on tumour size at diagnosis ("no association between dental check frequencies ≥ 12/12 and < 12/12 and a diagnosis of oral cancer and precancer") (Jullien et al., 1995). The retrospective case-series study, based in tertiary care hospital clinics in Iowa City, US (involving n=53 participants) concluded that increasing the interval to more than 12 months may significantly increase the size of tumours at diagnosis ("decreasing dental check-ups frequencies (>12/12 only and for intervals decreasing by ≥ 12/12) may results in a significantly increased tumor size and more advanced stage at diagnosis") (Rubright et al., 1996; Appendix 3.17).

However, overall, the systematic reviews concluded that there was limited evidence to support or refute the practice of six monthly dental check-ups, although this final conclusion was based mainly on dental caries data.

Low quality systematic reviews

None of the systematic reviews rated as lower quality considered the frequency of undertaking COE for early detection or screening of oral cancer.

3.5.4.2 Clinical Guidelines – Frequency of Conventional Oral Examination

High quality clinical guidelines

Only one of the six high quality-rated clinical guidelines included details of the frequency of COE for early detection and screening (National Institute for Clinical Excellence, 2004).

The NICE (2004a) clinical guideline on dental recall intervals recommended that the interval between oral health reviews should be based on the patient's needs, on the basis of disease levels and risk from the disease. For oral cancer risk assessment the guideline recommends that this should include tobacco and excessive alcohol history as well as the presence of OPMD identified via a COE; and that following a risk assessment dentists should then use their clinical judgement to weight these factors (along with other dental

risks) to determine the recall interval. They suggested that patients identified at high risk of oral cancer should have a COE and history at between 3 and 6 months intervals, and those at low risk could have intervals increased to between 12 and 24 months. These recommendations were rated "grade D" and considered a "Good Practice Point" (Table 3.13). This was based on expert consensus, which was collated via a robust methodological approach, however, there were no specific research studies associated with oral cancer cited in the document (because there were no high-quality studies available).

The high quality-rated clinical guideline from NICE (2004a) was the only guideline which provide a detailed description on recall intervals considering COE for early detection of oral cancer – proposing a risk based recall interval.

Table 3.13 High Quality Clinical Guidelines – Frequency

CG -ID	Year	Recommendations	Evidence Rating
NICE (2004a)	2004	"The recommended interval between oral health Reviews should be determined specifically foreach patient and tailored to meet his/her needs, on the basis of an assessment of disease levels and risk of or from dental disease" [Grade D] "During an oral health review, the dental team (led by the dentist) should ensure that comprehensive histories are taken, examinations are conducted and initial preventive advice is given. This will allow the dental team and the patient (and/or his or her parent, guardian or career) to discuss, where appropriate: the patient's ability or desire to visit the dentist at the recommended intervals" [Grade GPP] "The shortest interval between oral health reviews for all patients should be 3 months" [Grade GPP] "The longest interval between oral health reviews for patients younger than 18 years should be 12 months" [Grade GPP] "The longest interval between oral health reviews for patients aged 18 years and older should be 24 months" [Grade GPP] "Dentists use clinical judgement to weigh the risk factors and protective factor when deciding on a patient's recall intervals." [Grade GPP]	Grade D "Evidence Level 3 **or** 4 Or Extrapolated evidence from studies rated as [Level] 2+ **or** Formal consensus" Level 3= Non-analytic studies (e.g. case reports, case series) Level 4 = Expert opinion, formal consensus. Level 2+ = Well-conducted case-control or cohort studies with a low risk of confounding, bias or chance, and a moderate probability that the relationship is causal. Grade GPP = Good practice point.

Moderate quality clinical guidelines

Five of the nine moderate quality-rated clinical guidelines provided information in relation to frequency of early detection / screening for OCC or OPMD (AHRQ, 2007; CDSBC, 2008; BDA, 2010; SDCEP, 2012; SCCN, 2013).

The South Australian Head and Neck Cancer Pathway (2013) recommend improving community awareness by promoting 6 to 12 month dental and medical examinations with appropriate health questionnaires. However, what this examination included was not clarified in this guideline, and this recommendation was not based on any evidence.

SDCEP (2012) recommended a comprehensive oral health assessment, which included assessment of head and neck and oral mucosal tissue, every 24 months for adults (>18 years), and 12 months for children. This recommendation was based on the experience and knowledge of the guideline development group. However, these clinical guidelines did recommend "Focused Oral Health Reviews (FOHRs)" to be carried out within the 24 months interval, and that "both the number of FOHRs and the intervals between them will vary depending on the patient's risk of future oral disease." The guideline refers to the National Institute for Clinical Excellence, (2004) intervals, however, it does explicitly set out how oral cancer risk and COE assessment is included.

The BDA occasional paper guideline on early detection and prevention of oral cancer (2010), recommended opportunistic screening should be at the beginning of each new course of treatment, although they noted in relation to oral cancer that "since the objective is opportunistic case finding rather than invitational screening, there is no precise answer to a question about the desirable intervals between mouth examinations". They suggest that the interval should vary based on risk – without clearly indicating how this relates to oral cancer, and they cite the Health Development Agency's consensus statement on the Scientific Basis of Dental Health Education as evidence (Levine, 1996), and they also recommended that dental teams should follow the NICE (2004a) clinical guidance on dental recall intervals (Appendix 3.18).

The British Columbia (2008) clinical guideline on early detection for oral cancer, recommended that on the basis of present evidence and potential benefit, systematic oral cancer screening should be offered annually to all individuals from the age of 40. However, the details of the evidence were not provided.

The Agency for Healthcare Research and Quality (2007) recommended that inspection of the mouth, oropharyngeal soft tissues and head and neck lymph nodes should be conducted at each dental hygiene visit and that individuals with risk for oral cancer would require more frequent recall intervals. No additional detail was provided and the recommendations were not based on any cited evidence.

Collectively, the moderate clinical guidelines gave a very mixed picture of recall interval in relation to performing the COE – with the more recently published guidelines proposing a risk based recall interval.

Low quality clinical guidelines

One low quality rated clinical guideline recommended a frequency for oral cancer early detection / screening activities (MSCC, 2014).

The MSCC (2014) clinical guideline recommended that a yearly physical examination of the head and neck and oropharynx should be undertaken by a primary care physician and similarly a yearly clinical oral examination should be carried out by a primary care dentist. This low quality-rated clinical guideline recommended building oral cancer COEs into routine dental check-ups (Appendix 3.19).

3.5.5 Theme Four: Adjunct Tools

In addition to the conventional visual and tactile oral examination (COE), a number of adjunctive techniques or methods have been proposed and evaluated to try to improve the early detection of OCC and OPMD in primary care dental settings. These techniques include: vital rinsing or staining, light-based detection, exfoliative cytology, and blood and saliva analysis.

Vital staining techniques use a number of dyes which aim to stain areas of the oral mucosa with cells that have a high reproductive rate, such as dysplastic or neoplastic cells. Their main uses seem to be to indicate the area of the oral mucosa that needs to be examined and biopsied. Examples of dyes include toluidine blue, methylene blue, and Lugol's Iodine staining (Carreras-Torras and Gay-Escoda, 2015).

Light-based detection methods use devices which are based on the principle of differential tissue reflectance and tissue auto-fluorescence in normal and dysplastic areas of the oral

mucosa, and thus aim to improve the examination procedure. Examples include Velscope (tissue fluorescence imaging), ViziLite plus (chemiluminiscence), and tissue fluorescence spectroscopy (Rethman et al., 2010).

Both the vial staining and light-based detection system adjunct methods basically work under the assumption that abnormal mucosal tissue which is undergoing some metabolic or structural changes have different levels of absorbance and reflectance when they are exposed to different types of light or energy (Lingen et al, 2008).

Exfoliative cytology, via a brush biopsy, is a minimally invasive adjunct method to collect cells from the oral mucosa (Lingen et al, 2008).

Furthermore, there are blood and saliva analyses Adjunct Tools that require laboratory analysis to identify biomarkers (such as transcriptomic and proteomic markers) which are proposed to be discriminatory for detecting (squamous cell) oral cavity cancer (Markopoulos et al., 2010).

3.5.5.1 Systematic Reviews

High quality systematic reviews

Walsh et al (2013) in their high quality Cochrane review of assessment methods for the detection of oral cavity cancer and potentially malignant disorders found only one RCT among the 13 test accuracy trials they included, which assessed an adjunct method (Table 3.14). This community-based trial by Su et al (2010) in Taiwan, directly evaluated COE and vital rinsing, and there were no eligible diagnostic test accuracy studies evaluating light-based detection or blood or salivary sample analysis. The community-based trial included 7,975 participants and directly compared COE with COE plus vital rinsing. It reported a slightly higher detection rate for oral cavity cancer in the COE plus vital rinsing adjunct trial arm. However, overall, the systematic review authors concluded, based on this single trial (which was rated as having “unclear” risk of bias due to patient selection) with its marginal effects, that there was insufficient evidence in relation to the use of vital rinsing as part of a screening programme or early detection in primary care.

The effectiveness of current screening methods, including visual examination, toluidine blue, fluorescence imaging or brush biopsy, in decreasing oral cancer mortality were also assessed by Brocklehurst et al (2013). This high quality Cochrane review did not find any

RCTs which investigated the role of adjunct methods in screening for the early detection of oral cancer.

Similarly, Epstein and colleagues (2012) conducted a high quality systematic review focusing on the effectiveness of the COE and included the use of adjuncts in predicting oral cancer or OPMD. Unlike Cochrane, they did not limit their inclusion criteria to RCTs and included 24 studies (with 7,079 patients) assessing COE and the use of adjunctive techniques. However, they concluded, that while adjunct tests are potentially needed (due to OCCs often being detected or diagnosed at a late stage) to increase the ability ("diagnostic yield") of COE to identify early lesions, such techniques or indeed research and the evidence on such techniques are not yet available.

As part of the process of the American Dental Association clinical guidelines update (ADA, 2017), the guideline development team collaborated with the Cochrane Oral Health Group to update earlier Cochrane reviews (Walsh et al., 2013; and Macey et al., 2015) to assess the effectiveness of adjuncts for the evaluation of potentially malignant disorders in the oral cavity. This systematic review was separately published (Lingen et al., 2017). It should be noted here that the Macey et al. (2015) Cochrane review was excluded from this current overview on the grounds that it was focused in secondary rather than primary care, and on diagnosis rather than early detection, assessing the role of adjuncts in relation to biopsy / histopathological assessment, and was out of scope for this overview. In any case, however, the Macey et al. (2015) Cochrane review found that the quality of studies investigating adjunct tests was poor, and that no adjunct test would replace the standard clinical oral examination in guiding traditional scalpel biopsy and histological assessment. Lingen et al. (2017) found that adjuncts had limited diagnostic test accuracy when it is used as an alternative in the primary care settings. Lingen et al. (2017) also reported low quality evidence (including serious risks of bias among studies) suggesting cytology testing of suspicious lesions appeared to have the highest accuracy among adjuncts (sensitivity 0.92; and specificity 0.94); however they concluded that OHCPs should “remain skeptical about the potential benefits of any adjunct in clinical practice” particularly in primary care dental settings for early detection / screening of oral cavity cancer.

Overall, the summary of high-quality systematic reviews points to insufficient available evidence to draw conclusions of effectiveness or to recommend the use of Adjunct Tools alongside or instead of COE to improve the early detection of OCC and OPMD.

Table 3.14 High quality Systematic Reviews - adjuncts tools

Study ID	Results and/or Conclusions
Walsh et al (2013)	"One study (7975 participants) directly compared COE with COE plus vital rinsing in a randomised controlled trial. This study found a higher detection rate for oral cavity cancer in the conventional oral examination plus vital rinsing adjunct trial arm." "… overall, risk of bias for this study (Sue 2010) which directly compared two index tests in a randomised controlled trial to be at unclear risk of bias for patient and index test, Concern regarding the over all applicability of the study was high." "… other tests include the use of a blue 'dye', illumination with a special light and self examination by the individual. The review found a lot of variety in the ability of the different tests to differentiate between healthy mouths and non-referable lesions and more serious lesions or oral cancer. Overall, visual examination by a front-line health worker proved to be the best method. Between 59% and 99% of mouth cancers were detected, although sometimes normal tissue was mistaken for oral cancer. The remaining techniques examined were not as good at detecting mouth cancer and identified less than a third of cases."
Brocklehurst et al (2013)	" … there was no evidence to support the use of adjunctive technologies like toluidine blue, brush biopsy or fluorescence imaging as a screening tool to reduce oral cancer mortality."
Epstein et al (2012)	"… a COE of mucosal lesions generally is not predictive of their histologic diagnosis. The fact that OSCCs often are diagnosed at an advanced stage emphasizes the need for improving the COE and the need to develop adjuncts to assist in oral mucosal lesion detection and diagnosis".
Lingen et al (2017)	"Overall, adjuncts showed limited DTA when contextualized to be used in primary care settings. The main concerns are the high rate of false-positive results and serious issues of risk of bias and indirectness of the evidence. Low-quality evidence suggests that cytologic testing seems to *be* the most accurate adjunct among those included in this review." "Pooled sensitivity and specificity of adjuncts: for the evaluation of innocuous lesions ranged from 0.39 to 0.96, for the evaluation of suspicious lesions ranged from 0.31 to 0.95." "Cytologic testing used in suspicious lesions appears to have the highest accuracy among adjuncts … Sensitivity = 0.92 (95%CI 0.86 to 0.98); Specificity = 0.94 (95%CI 0.88 to 0.99); …low-quality evidence." "Clinicians should remain skeptical about the potential benefit of any adjunct in clinical practice."

Moderate quality systematic reviews

There were three systematic reviews rated as moderate quality which assessed the role of Adjunct Tools in the early detection of OCC (Patton et al., 2008; Downer et al., 2004; Gray et al., 2000).

The Patton et al. (2008) review assessed the effectiveness of a number of Adjunct Tools to the standard visual and tactile oral examination. They found 23 studies (with a range of study designs) in total, with most (n=15) focusing on toluidine blue. While concluding there was limited evidence for adjuncts overall, they did find that toluidine blue had a potential role in improving early detection among high risk populations. However, on further examination of their data, high risk was defined as those attending "oral mucosal disease clinics" where there was higher underlying prevalence of OPMD. Therefore, this evidence is more applicable to its use as a diagnostic aid in a secondary care setting, rather than early detection in primary care (Appendix 3.20)

On the other hand, Downer and colleagues (2004) conducted their systematic review on test performance in screening in apparently healthy individuals for oral cancer and precancer in primary care. The review focused on the COE examination and they found no evidence of the effectiveness of toluidine blue dye as an adjunct technique to COE, and they concluded that the use of the toluidine blue would not be beneficial in primary care settings (Appendix 3.20).

Gray et al. (2000) also focused only on vital staining / toluidine blue for oral cancer screening in primary care. In addition to effectiveness, they assessed the cost-effectiveness of toluidine blue. They identified 14 studies in secondary care and one in primary care (not dental primary care). All secondary care studies were in high risk populations of clinical cohorts with oral mucosal lesions – and there was a wide range of sensitivity and specificity reported (no meta-analyses was performed). The one primary care study was underpowered to create an effect. In addition, in their economic analysis, the costs per case detected and per person cured were extremely high (Appendix 3.20).This systematic review concluded that toluidine blue as an adjunct to COE in primary dental care was neither effective nor cost-effective.

Overall, these moderate quality systematic reviews have a greater focus on toluidine blue (than on other adjuncts). Taken together, the evidence does not support the use of Adjunct

Tools (including toluidine blue) in primary dental care settings for the early detection of OCC and OPMD.

Low quality systematic reviews

The systematic review conducted by Patton (2003), which was rated as low quality, focused on community-based (primary care) screening programmes. Patton assessed the evidence as "fair" on the use of toluidine blue as a diagnostic tool for oral precancerous lesions; and concluded that there was evidence that toluidine blue was effective as a diagnostic tool in high risk individual and suspicious mucosa lesions. This conclusion was based on high sensitivity and specificity ranges from included studies (Appendix 3.21). However, on closer inspection, these studies were set in specialist/referral practices, i.e. settings with an aim of toluidine blue guiding "diagnosis". The Patton (2003) review does conclude that there is insufficient evidence for adjunctive techniques in relation to improving detection of oral malignancies in community screening programmes.

In relation to cytological techniques and molecular analysis, Carreras-Torras and Gay-Escoda (2015) undertook a more recent, but lower quality rated systematic review. They provided a detailed description of potential adjunct methods for early detection of OCC and OPMD, which including more recent developments in cytological techniques, molecular analyses, imaging and genetic studies techniques. They concluded there was insufficient scientific evidence on the use Adjunct Tools for the early detection of OCC or OPMD. They also concluded that toluidine blue, due to its high sensitivity and low specificity, was not suitable as part of screening in primary care, but they did consider it as having a potential role in supporting biopsy procedures in secondary care / specialist settings (Appendix 3.21).

Overall, it appeared that the historic lower quality systematic reviews highlighted evidence for the potential role of toluidine blue for early detection of oral cancer particularly in high risk populations. A deeper inspection of the data and studies used in these systematic reviews show that these high risk populations were patients already in specialist / referral clinics or secondary care with a suspicious OPMD and were not attending for routine primary dental care nor invited as part of a screening programme. Therefore, the lower quality reviews did not support the use of Adjunct Tools in early detection of OPMDs or OCCs.

3.5.5.2 Clinical Guidelines

High quality clinical guidelines

Out of six high quality rated clinical guidelines, only three considered the use of adjunctive screening aids to assist the clinician with the detection of early cancerous changes (SIGN, 2006; USPSTF, 2014; ADA, 2017).

The US Preventive Services Task Force (USPSTF, 2014) produced a high quality clinical guideline in relation to screening for oral cancer in primary care. The recommendations focused on screening of the oral cavity of asymptomatic adults aged 18 years or older by primary care providers. They concluded that all the adjunct methods, including toluidine blue, chemiluminescent, auto-fluorescent lightening, and brush cytopathology, had not been adequately tested, and therefore they did not make any recommendations for their use (Table 3.15). Specifically, in relation to toluidine blue, they reported it was not found to significantly improve screening for OPMD or OCC and did not improve outcomes. No acceptable evidence for other adjunctive devices was found in the literature reviewed.

The ADA (2017) clinical guideline was a high quality update of ADA (2010). Part of the guideline development process involved undertaking a robust (high quality) systematic review of the role of adjuncts and this was published separately and has been included above (Lingen et al., 2017). The recommendations largely reflect the findings of their systematic review. The clinical guideline provided a number of recommendations addressing a range of clinical questions in relation to the role of adjuncts (Table 3.15). The guideline did not recommend the use of any vital staining, auto-fluorescence, tissue reflectance, salivary, or other adjuncts to identify or as they describe it “to triage” in primary care for OPMD or OCC in either healthy adults with symptoms or oral mucosal lesions (whether these were suspicious or not). The only potential proposed use of adjuncts related to the role of cytological adjuncts in the evaluation of OPMD among adult patients with “clinically evident seemingly innocuous or suspicious lesions” and only when a patient declined the clinical recommendation of referral to a specialist / biopsy of lesion. In this scenario, the guideline recommended that a primary care clinician could use a cytological adjunct (e.g. “brush biopsy”) to provide additional lesion assessment, with a positive or atypical cytological test reinforcing the need for a referral / biopsy. A negative test would indicate the need for periodic follow-up of the patient. The strength of this

cytological adjunct recommendation was described as "conditional" and based on low quality evidence "with serious issues of risk of bias" (Table 3.15).

The SIGN clinical guideline on diagnosis and management of head and neck cancer (2006) acknowledged the lack of evidence to support the use of toluidine blue in primary care dental settings. The guideline based this recommendation on the clinical experience of the guideline development group.

In summary, the high quality clinical guidelines did not support the use of different adjunct methods in primary care dental settings, and this was due to an absence of evidence of effectiveness.

Table 3.15 High Quality Clinical Guidelines – Adjunct Tools

CG –ID	Recommendations	Evidence Rating
ADA (2017)	Recommendation 3: The panel does not recommend cytologic adjuncts for the evaluation of potentially malignant disorders among adult patients with clinically evident, seemingly innocuous, or suspicious lesions. Should a patient decline the clinician's recommendation for performing a biopsy of the lesion or referral to a specialist, the clinician can use a cytologic adjunct to provide additional lesion assessment. A positive or atypical cytologic test result reinforces the need for a biopsy or referral. A negative cytologic test result indicates the need for periodic follow-up of the patient. If the clinician detects persistence or progression of the lesion, immediately performing a biopsy of the lesion or referral to a specialist is indicated. "Recommendation 4: The panel does not recommend autofluorescence, tissue reflectance, or vital staining adjuncts for the evaluation of potentially malignant disorders among adult patients with clinically evident, seemingly innocuous, or suspicious lesions."	"Quality of evidence: Low" "Strength of recommendation: Conditional" "Low: Our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect." "Conditional: Recognize that different choices will be appropriate for individual patients and that you must help each patient arrive at a management decision consistent with his or her values and preferences. Decision aids may be useful helping patients make decisions consistent with their values and preferences." "Quality of evidence: Low to Very low" "Strength of recommendation: Conditional" "Very low: We have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of the effect."
USPSTF (2014)	"… additional tests proposed as adjuncts to the oral cancer screening examination include toluidine blue dye staining, chemiluminescent and autofluorescent lightening device and brush cytopathology. These screening and adjunct tests have not been adequately tested in primary care…"	I statement – Based on conclusion that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

SIGN (2006)	"There is no evidence for an effective screening programme for head and neck cancers, in particular, toluidine blue dye does not appear to be a cost – effective method of screening for oral cancer in primary care (dental) setting"	Good Practice Point – Based on the clinical experience of the guideline development group.

Moderate quality clinical guidelines

There were four moderate quality clinical guidelines which provided some statements in relation to the use of adjunctive methods for the early detection of oral cancer and OPMD.

The Agency for Health care Research and Quality (AHRQ, 2007) clinical guideline did not recommended the use of toluidine blue as part of a screening examination, stating that it did not improve detection of lesions. It could not identify any studies of other adjuncts that met the inclusion criteria (Appendix 3.22).

The College of Dental Surgeons of British Columbia (CDSBC, 2008) clinical guideline recommended (based on expert opinion) the use of adjunctive tools (toluidine blue and direct fluorescence visualisation) to complement the COE for helping to identify OPMD and OCC lesions. This recommendation was aimed at both primary care dentists undertaking the annual oral cancer screening examination or at the time of identification of any suspicious lesion (Appendix 3.22).

The British Dental Association (BDA, 2010) stated that there was not sufficient evidence of effectiveness of adjuncts in primary care, and that while sensitivity for adjuncts was high the specificity remained low. They recommended a thorough visual and digital examination for early detection of OPMD / OCC. However, they did state that while "a soft tissue examination without the use of adjunct will be completely adequate" they indicated that the use of adjuncts had a potential role in increasing the accuracy of an examination among "high risk patients without obvious lesions" and that "there is also a possible benefit in the way the use of an adjunct raises patient awareness" (Appendix 3.22). The evidence in support of these statements was limited and selective with only the Patton et al. (2008) systematic review being cited, and another narrative review by Lingen et al. (2008).

The Solutions for Public Health (2015) reviewed screening for oral cancer against the UK National Screening Committee (NSC) criteria for appraising the viability, effectiveness, and appropriateness of a screening Programme (NSC, 2003). They could not identify sufficient scientific evidence to support adjuncts to COE including vital rinsing, light-

based detection, and biomarkers, used singly or in combination to detect oral cavity cancer and OPMD. They did not recommend the use of adjunctive tools for early detection of OCC and OPMD.

Overall, the moderate quality-rated and more recently published clinical guidelines did not recommend the use of the adjunctive tools to COE in early detection of oral cavity cancer or OPMDs in primary care settings. Earlier clinical guidelines were perhaps getting ahead of the evidence-base in proposing the role of vital staining adjuncts, which were not borne out either by the evidence or continued in subsequent years.

Low quality clinical guidelines

The Glasgow University Dental School (2003) guideline was only the lower quality clinical guideline that indicated a role for the use of an adjunct in early detection of OCC. The guideline recommended that the technique had some limited use in specialist centres. It was not entirely clear, but likely, that this use was in relation to guiding diagnostic biopsy in specialist centres. However, the guideline was clear for primary health care settings, where it recommended that screening should be done via visual examination to detect any abnormalities (Appendix 3.23).

3.6 Synthesis of Theme Findings

This section brings together the syntheses of the four key themes covering both systematic reviews and clinical guidelines and compares and contrasts their findings.

3.6.1 Evidence of the Effectiveness of Conventional Oral Examination in Early Detection / Screening of Oral Cavity Cancer

The high quality systematic reviews consistently showed broadly similar findings. They were in agreement that there was limited evidence of the effectiveness of the conventional oral examination (COE) in identifying oral potentially malignant disorders and oral cavity cancer. What evidence that was available, showed a tendency for this to be more effective in both high prevalence populations and also when performed in high risk individuals (defined as those who use tobacco and consume alcohol). However, this evidence of the effectiveness was largely drawn from a single large randomized controlled trial (Sankaranarayanan et al., 2005) undertaken by community health care workers in a high

OPMD prevalence / high OCC incidence country (India), albeit the effectiveness in terms of reduced mortality was observed in high risk individuals. The application of this evidence to primary care dental settings in lower incidence countries is a pragmatic one based on expert opinion of this and other more limited studies.

The high quality clinical guidelines reflected the systematic review, with their clinical recommendations not extending beyond the systematic review findings. There was a tendency for the lower quality guidance documents, which took an expert opinion approach, to better describe or detail the COE process, for which the evidence base is even more limited and which warranted a more practical approach.

There were no systematic reviews or references within them to trials on the method or content of the COE – covering for example: i) how to examine and / or palpate all relevant sites of the head and neck, and all sites of the oral cavity, ii) the type of light to use, whether to use gauze or dental mirrors, iii) symptom and sign checklists and how to record / capture examination findings on clinical records, and iv) consideration of which dental professionals should perform COE and how they should be trained. However, the lower quality clinical guidelines did set out aspects of how to perform the COE, but none did so comprehensively, covering all of the different examination aspects.

3.6.2 Evidence of Whether Conventional Oral Examination Should be Delivered Targeted, Universally or Opportunistically

In summary, the high quality systematic reviews reported there was a lack of evidence in relation to whether there should be any form of targeting of early detection / screening for oral cancer. There was a particular absence of randomised control trials (RCTs) in this area, but the difficulty in conducting such trials was acknowledged. The systematic reviews noted that a targeted approach could potentially be attractive from effectiveness and especially cost-effectiveness perspectives, however, the lack of high quality evidence meant that a need for a more precautionary approach to undertaking a COE in all patients attending primary (dental) care was generally concluded (albeit there was not specific evidence to support opportunistic screening). It was recognized that there remain challenges in increasing the attendance levels for these opportunistic examinations, particularly among high risk groups.

The clinical guidelines seemed to have universal agreement that COE ought to be performed opportunistically on all patients attending for dental check-up appointments, and that while the higher quality-rated clinical guidelines suggested that oral cancer risk assessment should be undertaken at the same time, they did not go so far as to recommend a different COE approach or focus dependent on the outcome of the risk assessment. The lower quality guidelines seemed to indicate greater vigilance or higher degree of suspicion should be brought to performing the COE on higher risk individuals, but details of what this would involve were absent as was the evidence to support these statements.

Overall, the high-quality rated clinical guidelines included recommendations which reflected the (albeit limited) systematic review evidence base fairly well. Both the clinical guidelines and systematic reviews reported a lack of evidence base and did not make recommendations for a population screening programme (even a targeted or stratified one). There was insufficient evidence available for such a programme to meet the screening programme criteria (WHO Wilson, Jungner, 1968; NSC, 2003). The clinical guidelines did not make recommendations which over-reached the evidence available, and they did tend to suggest the opportunistic approach in primary care dental settings for both “all” patients and high-risk patients should be similar. However, they did suggest that patients’ oral cancer risk status should be ascertained - through the use of a smoking and alcohol consumption history.

3.6.3 Evidence of the Frequency of Recall Interval for Undertaking a Conventional Oral Examination

Overall, in terms of the frequency of conducting an oral cancer examination, the practice has been traditionally to examine a patient every six months. The limited body of systematic reviews identified concluded that there was a very limited evidence base regarding recall intervals and more high-quality systematic reviews and clinical trials were required to determine the frequency of the recall interval, including in relation to oral cancer early detection / screening.

There was a very limited evidence base on the frequency of undertaking oral cancer early detection / screening COEs, which seemed to be put down to the complexity of testing this via a RCT.

The clinical guidelines developed their recommendations for best practice from expert opinion when the evidence was more limited. The one high-quality clinical guideline (National Institute for Clinical Excellence, 2004) pointed towards supporting the determination of the frequency of COEs on a risk basis. For example, where the patient smokes and / or consumes alcohol the recall interval should be shorter (3-6 months) than for patients at lower risk (between 1 and 2 years). There was less consensus from the lower quality clinical guidelines, which tended to suggest a yearly COE. Clinical guidelines also tended to recommend that oral cancer early detection / screening should be an opportunistic and integral part of routine dental check-ups.

3.6.4 Evidence for the Role of Adjunct Methods to the Conventional Oral Examination

Overall, there was a lack of evidence for the role of adjuncts (to the conventional oral examination) in primary care. The systematic reviews overall, but especially the high quality-rated systematic reviews did not provide convincing evidence to support their use. It was interesting to note that reviews with increasing risk of bias (moderate quality) and from earlier times, reported more support for the role of toluidine blue in early detection of oral cavity cancer and OPMD. The high quality clinical guidelines were in agreement with the evidence-base in the high quality systematic reviews and did not recommend the use of Adjunct Tools to COE for early detection of OCC or OPMD. These guidelines reported that only low grade evidence was available to support the use of adjuncts in general dental practice. Both the most historic (NCCDPHP, 1996) and most recent (ADA, 2017) clinical guidelines were recommending adjuncts – toluidine (vital staining) and cytology (brush biopsy), respectively. They both referenced the evidence-base, but the more recent, higher quality ADA (2017) clinical guidelines acknowledged the significant limitations of the evidence.

While outwith the scope of this overview, there was a clearer role and consistency in the clinical guidelines, if not necessarily supported by a direct evidence base in the systematic reviews, for the role of adjuncts to support and guide the clinical biopsy / histopathological assessment of oral mucosal OPMD or OCC lesions.

Conversely, there were no (positive) findings / recommendations reported in the systematic reviews, which were absent from the clinical guidelines.

3.7 Strengths of this Overview

This overview chapter took a robust systematic approach in an attempt to identify the best practice for early detection / screening of oral cavity cancer in primary dental care. While there are many reviews and editorials written on this topic (Kujan et al., 2005; Cicciù et al., 2019; Psoter et al., 2019), to the thesis author's knowledge, this is the first attempt to apply a systematic overview approach. The methods have been peer-reviewed as the protocol has been published and include the novel approach of systematically reviewing systematic reviews and clinical guidelines simultaneously (Al Bulushi et al. 2016).

A taxonomy of how to consider the evidence was developed to guide the overview, this included key aspects, domains, or themes of the practice of early detection / screening, namely: the clinical oral examination assessment, whether it should be targeted or different in higher risk groups, the frequency of assessment, and the evidence for the role of adjunct methods to the clinical oral examination.

A thorough systematic search developed in collaboration with a subject specialist librarian using multiple databases was used to identify systematic reviews on oral cancer early detection / screening. In addition, databases were searched for clinical guidelines as well as searching the internet for clinical guidelines from a long list of clinical, health, and professional organisations. Screening of titles, abstracts, and full text papers / document was undertaken by two assessors.

Comprehensive quality appraisal of the included systematic reviews was performed (by three assessors) using two instruments (AMSTAR and ROBIS). While there was not much difference between the systematic reviews which scored high on AMSTAR and low risk of bias on ROBIS, this dual quality assessment process provided greater clarity on the quality of the systematic reviews – particularly those of highest quality. Quality appraisal of the clinical guidelines was also undertaken by three assessors using the AGREE II tool. This is a recently rigorously developed instrument (Brouwers et al., 2010), which has a detailed training manual to guide and standardise assessment of the quality of clinical guideline documents.

As there were no quantitative data to perform a meta-analysis, a narrative data synthesis of the findings of the systematic reviews and the recommendations of the clinical guidelines was performed. This narrative synthesis gave primacy to the quality of systematic review and clinical guidelines and the recency of their publication. It was undertaken within the

early detection / screening domains developed, and systematic reviews and clinical guidelines were cross-compared and contrasted.

This overview approach of combining the systematic reviews and the clinical guidelines was novel, but was done out of necessity on several counts: the multiple systematic reviews (but the dearth of original research studies available for these systematic reviews), and the large quantity of clinical guidelines from around the world available on this topic. It is worth pointing out that these systematic overview approaches are going to be increasingly required and further developed as science and literature expands. There are often multiple systematic reviews in the published literature some of which are updated sequentially, but some are overlapping in time-frames of original studies included or in the focus or angle of the review. Therefore combining, synthesising, and distilling the evidence is going to be an ever increasing challenge.

3.8 Limitations of this Overview

There were a number of limitations to the overview and they will be discussed here. Such limitations are well described in the literature on methods for systematic reviews (e.g. as highlighted in early versions of the Cochrane Handbook - Higgins and Green, 2006). The primary issue is the same as for all systematic reviews, namely they are dependent on the quality or level of evidence of the original studies included in them. This is a similar, if not greater issue, for systematic overviews, which are once again removed from the original studies or trials. However, it is anticipated that a good quality systematic review (in its synthesis, findings, and conclusions) takes into account the quality of the original studies. Thus, it aims to mitigate for over or under emphasising the quality or strength of the evidence base. During the synthesis process in this thesis overview, this tension, between the systematic review and the original source studies, manifested in the thesis author being drawn into looking closely at and sometimes reviewing the original studies within the systematic reviews. An alternative overview approach could have been to have taken out the middle-man – i.e. the systematic reviews themselves and gone straight to the source studies from the outset. However, this would seem somewhat a duplication of effort of many of the identified systematic reviews that have gone before in this area, including several Cochrane reviews, and would probably have been out with the scope or feasibility of a PhD thesis - requiring a large team approach, as per the Cochrane review approach.

Another related issue that had to be borne in mind was data duplication, there were several original studies that appeared in several of the systematic reviews. Care had to be taken not to over emphasis their findings. In some ways the lack of original underpinning source studies limited this issue.

In late 2018 a special edition of BMC Systematic Reviews outlined many of the methodological issues with systematic overviews (McKenzie, 2018).These included overlap reviews, outdated reviews, quality assessment of the included reviews, publication bias, GRADE schemes (Pollock et al., 2017).

Problems with narrative synthesis are well recognised in systematic reviews as described in the Cochrane Handbook "Non-statistical syntheses … are challenging, however, because it is difficult to set out or describe results without being selective or emphasizing some findings over others." (Higgins and Green, 2011). The Cochrane Handbook goes on to suggest that one way around this is to set out in the review protocol the plan of narrative synthesis and reporting. This was done as part of the published protocol (Al-Bulushi et al., 2016), but this is not in itself sufficient to address the complexity of narrative synthesis methods. More recent reporting and methods have very recently been developed – Synthesis without meta-analysis (SWiM) in systematic reviews: reporting guideline by colleagues at the University of Glasgow (Campbell et al., 2020). Some of the items of the SWiM guidance had been followed in this overview (i.e. item 1 – grouping the study types, item 3 and 4 describing the synthesis methods in a protocol and identifying priority criteria, and item 8 presenting the evidence - as in the narrative data extraction tables in Appendices 3.4 and 3.5). However, some of the items (items 2, 6 and 7 related to defining outcome criteria and heterogeneity) would not necessarily apply in this overview, which had broader dimensions than a simple outcome metric. The SWiM method could have improved the narrative synthesis analysis using its focus on the certainty of evidence. However, there is an expectation in SWiM that this certainty of evidence is itself assessed by a stakeholder jury voting on the certainty of the evidence base.

Finally, there was a surprising lack of studies that went into detail about the clinical process for undertaking (and recording) a COE. However, the clinical guidelines were also not as specific on these detailed examination methods. On reflection, the source clinical guidelines documents were perhaps not the best suited to this level of detail, and training manuals or materials would have been better suited to this task.

3.9 Conclusions

The main findings of the systematic overview were a re-emphasis of the importance of a clinical oral examination for early detection / screening of oral cancer opportunistically at the time of the routine dental care appointment in primary care. Oral cancer screening does not meet the criteria for a population, invitational, or targeted formal screening programme. There was no evidence for the need or added benefit of adjunct methods (e.g. vital staining, light-based detection, biomarkers and brush biopsy). There was no evidence that a different or enhanced COE should be performed on patient who are at higher risk of oral cancer (i.e. those who smoke / use tobacco and / or drink alcohol), however, there is one high quality clinical guideline recommendation that higher risk patients should have their COE at a greater frequency (at least yearly). To identify those patients at risk, a tobacco and alcohol history risk assessment should be performed at the time of the clinical oral examination.

The next steps in the thesis research plan were to investigate the feasibility of implementing these findings with practitioners and patients in primary care dental practice in Scotland and Oman (Chapter 4 and 5).

Chapter 4: Qualitative exploration of the perceptions of oral health care professionals on early detection/ screening for OCC in primary care dental settings in Scotland and Oman

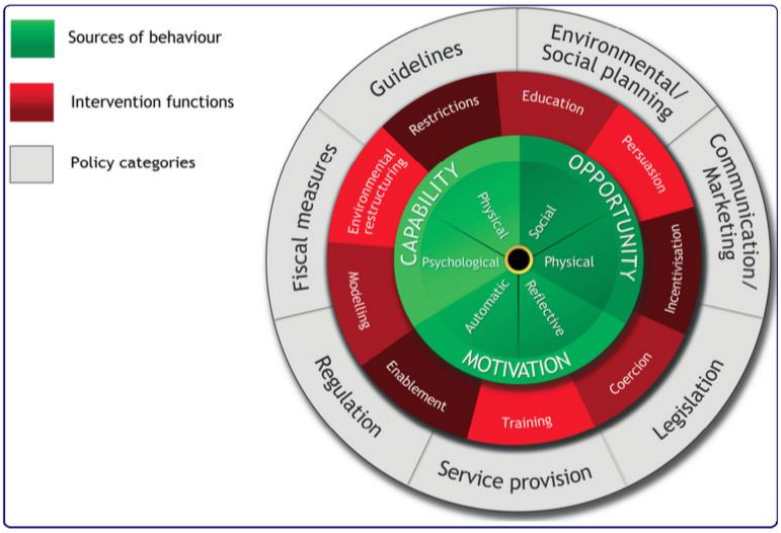
4.1 Introduction

As a follow-up to the systematic overview, this qualitative study was conducted with the aim of: a) exploring which components of the synthesized best practice evidence and clinical guidelines are reportedly implemented in current practice by oral health care professionals (OHCPs); b) assessing barriers to implementation towards recommendations for intervention to support evidence-based screening and early detection of oral cancer in general dental practice.

A seminal report by the US Institute of Medicine (Wolfe, 2001) underpins repeated efforts to understand the barriers that influence the translation of high quality evidence to adopted practice, which has now seen concerted effort under the umbrella term of 'implementation science'. Such barriers, covering individual dental practitioner attitudes and characteristics, organisational aspects such as time and resource, and social influences from patients, peers and stakeholders, have been observed in relation to a wide range of recommended dental practice including: standard precautions for exposure (Hedayati et al., 2014), antibiotic prescribing (Newlands et al., 2015), preventive management of caries (Templeton et al., 2015) and the provision of care for dependent older people (Göstemeyer et al., 2019).

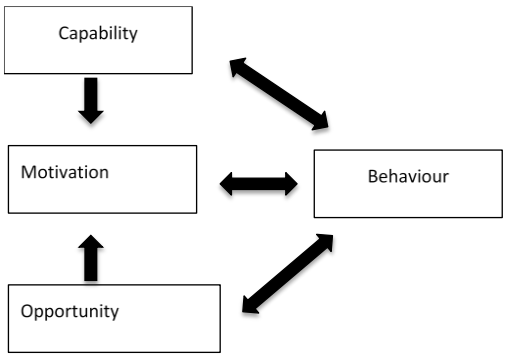
The best-known model for ensuring rigorous exploration of barriers (and facilitators - those factors which support rather than inhibit good practice) is a framework from health psychology known as the Behaviour Change Wheel (Michie, Atkins and West, 2014; Figure 4.1). It is in use across many different fields of health and medicine. For example, in paediatric health programmes (Alexander et al., 2014) and mobilization of vulnerable elders (Moore et al., 2014), in identifying barriers and facilitators to learning in the workplace in qualitative study (Lloyd et al., 2014), and vaccination and other antiviral medicine (Rubinstein et al., 2015). Moreover, it has been used to develop interventions and guidelines to modify health behaviours (Jackson et al., 2014; Lister, 2014; Atkins and Michie, 2015; Bérubé et al., 2015) and in systematic reviews to identify the mechanism of complex intervention for cancer pain (Marie et al., 2013; Arnott et al., 2014).

Figure 4.1 The Behaviour Change Wheel (Michie, Atkins and West, 2014)



The core of the BCW is the 'COM-B' psychological model (Figure 4.2) used to understand behaviours and help in providing a "behavioural diagnosis" (Michie et al., 2014). According to COM-B, an individual's behaviour is the result of an interaction between three main elements: the capability (C) in carrying out the behaviour, opportunity (O) to carry it out, and motivation (M) towards the behaviour (Michie et al., 2014).The general utility of the BCW comes from this diagnosis of what underlies behaviour and using that to drive appropriately targeted interventions (see Chapter 6).

Figure 4.2 COM-B Model (Michie, Atkins and West, 2014)



The model derives from initial work which resulted in the Theoretical Domains Framework (TDF). This consists of 14 behavioural domains (constructs) which are subsumed within the three arms of the COM-B model (Atkins and Michie, 2015). The TDF itself was produced from combining 128 constructs from behaviour change theories (Cane et al., 2012).

The arrows in Figure 4.2 represent the relationship between the three primary system constructs and the behaviour. The COM-B model elements are not discrete but often interconnected (i.e. if we change one element it will automatically change the other). For example, if we decrease the opportunity this may over time affect the motivation of the individual towards the behaviour (Michie et al., 2014). This framework has also been applied across many health care settings such as: to identify barriers in managing type 2 diabetes in primary care (Rushforth et al., 2016); in understanding clinicians' behaviour towards blood transfusion (Francis et al, 2014); in understanding surgeons' perceptions on routine pre-operative testing (Patey et al 2012); for physician Hand Hygiene Compliance (Squires et al, 2014); and in the development of an intervention to modify blunt chest injury management (Curtis et al, 2017).

In this study we have employed a pragmatic coding based on the more parsimonious / abstracted COM-B model within the BCW. In the following study in Chapter 5 with dental patients the same model is employed but there is also coding of the factors using the original TDF categories. Table 4.1 shows the TDF domains and the relation with the COM-B model coding.

Table 4.1 COM-B model constructs (from TDF Domains) adapted from Cane, O'Connor and Michie (2012)

TDF Domain	Original Definition	COM-B for this thesis
Knowledge	(An awareness of the existence of something)	Psychological Capability (C. Psy.) *Knowledge, confidence, awareness, ability to understand*
Skills	(An ability or proficiency acquired through practice)	
Memory, Attention and Decision Processes	(The ability to retain information, focus selectively on aspects of the environment and choose between two or more alternatives)	
Behavioural Regulation	(Anything aimed at managing or changing objectively observed or measured actions)	

TDF Domain	Original Definition	COM-B for this thesis
Skills	(An ability or proficiency acquired through practice)	Physical Capability (C. Phys.) *Technical / clinical skills*
Social influences	(Those interpersonal processes that can cause individuals to change their thoughts, feelings, or behaviours)	Social Opportunity (Op. Soc.) *Views of others such as patients and professional and cultural norm*
Environmental Context and Resources	(Any circumstance of a person's situation or environment that discourages or encourages the development of skills and abilities, independence, social competence, and adaptive behaviour)	Physical Opportunity (Op. Phys.) *Resources, time, money, training, guidance etc.*
Social/Professional Role and Identity	(A coherent set of behaviours and displayed personal qualities of an individual in a social or work setting)	Reflective Motivation (M. Ref.) *Reasoned behaviour such as learned from experience or interpretation of evidence*
Beliefs about Capabilities	(Acceptance of the truth, reality, or validity about an ability, talent, or facility that a person can put to constructive use)	
Optimism	(The confidence that things will happen for the best or that desired goals will be attained)	
Beliefs about Consequences	(Acceptance of the truth, reality, or validity about outcomes of a behaviour in a given situation)	
Intentions	(A conscious decision to perform a behaviour or a resolve to act in a certain way)	
Social/Professional Role and Identity	(A coherent set of behaviours and displayed personal qualities of an individual in a social or work setting)	Automatic Motivation (M. Auto.) *Basic views such as those driven by social/ professional identity; dispositional factors*
Optimism	(The confidence that things will happen for the best or that desired goals will be attained)	
Reinforcement	(Increasing the probability of a response by arranging a dependent relationship, or contingency, between the response and a given stimulus)	
Emotion	(A complex reaction pattern, involving experiential, behavioural, and physiological elements, by which the individual attempts to deal with a personally significant matter or event)	

Table 4.1 shows the six categories (right hand column) adapted from the models and used to guide the present interviews and interpretation in Chapters 4 and 5. This study and the following study with patients explored this range of influences in relation to the recommended practices for the early detection / screening for OCC by OHCPs identified in Chapter 3. The use of the framework ensured that interviews covered a range of potential influences on behaviour. Capability included, for example, the OHCPs capacity to engage in essential thought processes, (e.g., comprehension of the need for early detection / screening of OCC) as well as essential physical / technical processes (e.g., the capability to conduct a conventional oral examination). Opportunity included environmental factors that were enablers / facilitators of, or barriers to, the prescribed desirable behaviour, including physical factors (e.g., time, access to resources, cost, and training) as well as social factors (e.g., religious / cultural beliefs, norms of the professionals' roles). Finally, Motivation included reflective or emotional reasoning that encouraged or inhibited the OHCPs desirable behaviour. This can include, for example, beliefs and impulses arising from associated learning from previous cases / events, or more fundamental dispositions or orientations, such as a general drive towards preventive care, or otherwise.

The COM-B model was deemed an appropriate theoretical framework to underpin the data analysis, because it facilitated: a) structured explanation of why the adherence to best practice evidence and guidelines in relation to early detection for OCC was not necessarily implemented by all the OHCPs who participated in this research; and b) what steps might be taken towards improving uptake (Chapter 6).

4.2 Methodology

The research methodology for this chapter is broadly defined as phenomenological, because it is rooted in the fundamental idea that people's own experiences of a phenomenon of interest are important aspects to its reality (Denzin & Lincoln, 2008).

Phenomenology-inspired work when engaging professionals is relatively common, especially in nursing (Beck 1994), though there are debates as to whether the tradition is truly phenomenological (Zahavi and Martiny, 2019). This study explored and interpreted the self-reported lived experiences and perceptions of a purposive sample of OHCPs, focusing on issues of intentionality, emotionality, and conscious behaviour around the topic, using a first-person perspective. This attendance to personal views of practitioners is

important in implementation research where people are being asked to follow certain principles or guidelines. The research extracted the “essence” of the interview responses in the tradition of a phenomenological research design (Merriam, 2014).

4.2.1 Research Design

The aims were achieved by means of a qualitative methodology, adopting a naturalistic approach, in which the researcher explored the phenomenon of the early detection / screening of oral cavity cancer (OCC) in clinical settings, attempting to make sense of and interpret this phenomenon in terms of the lived experiences and perceptions of OHCPs (BDJ, 2010). The data were collected by conducting semi-structured interviews with a purposive sample of OHCPs working in primary dental services in two countries (Scotland and Oman).

All interviews for this thesis in Chapters 4 (professionals) and 5 (patients) were designed by the author, who also designed and carried out all analysis. Interviews in Scotland were carried out by another student who was examining behavioural risk factors and intervention (Mathur, 2019). The author of this thesis explored those issues in Omani interviews in a reciprocal arrangement. The ‘whole’ integrated interview (OCC screening plus behavioural assessment and advice) was piloted by the two researchers together.

Examination of care in different countries was important (Rosen et al, 2004), because all health care is practiced in a social and cultural context. It is also known inequality exists with intra- and extra-oral examinations being less likely for low educated / low income groups, and minority ethnic versus white groups (Gupta et al., 2019).

Variance in care, inequalities and / or disparities in health care may be associated with sociocultural differences that influence the providers' attitudes, expectations, and behaviour including clinical decision-making processes (Smedley, Smith, & Nelson, 2003; Park, 2013).

The reason for conducting a qualitative study, focused on the responses of OHCPs to open-ended interview questions, was that it provided an opportunity for an in-depth exploration of the topic, which could not be so easily addressed through a questionnaire / survey based on ‘fixed response’ formats, such as Likert scales (Green & Thorogood, 2009; Stewart et al. 2008).

The qualitative study enabled the researcher: a) to elicit how and why OHCPs made certain personal decisions regarding screening / early detection of OCC; and b) to gain sufficient detail to understand the facilitators or barriers of implementation of best practice evidence and guidelines. The role of the researcher in the interview procedure was to develop a rapport with the participants, to clarify the questions, to prompt and encourage detailed answers, and to gain a meaningful insight into the attitudes, beliefs, preferences, and 'lived experiences' of the participants (Merriam, 2014).

4.2.2 Population and Participants

In countries with universal or population coverage of primary care dental services, OHCPs have an important role to provide visual screening / early detection services as part of routine dental services (SIGN, 2006 and ADA, 2010). Consequently, OHCPs represented the most appropriate population of professionals to interview in order to achieve the aims of this study.

Semi-structured interviews were conducted with a total of 31 OHCPs providing primary dental services of which 13 were in Scotland and 18 were in the Sultanate of Oman. Female OHCPs (17) represented 54.8 % of the sample. Recruitment aimed to cover a wide range of experience; the average reported length of professional practice experience of the OHCPs was 15 years, with a wide range of 1 month to 36 years.

The rationale for choosing this non-probabilistic purposive sample is that participants can then inform a defined topic of which they have experience, providing empirical data. An important consideration of such samples is how large they should be. Data saturation (Walker, 2012; Fusch and Ness, 2015) occurs in qualitative research because the analysis of interview transcripts follows a 'law of diminishing returns'. That is, after a certain number of participants have been interviewed, little or no new information emerges.

The sample size used in this study (31 OHCPs) was considered sufficient to achieve saturation, following Green and Thorogood (2009; p120) who suggested that, in the context of health care research, "the experience of most qualitative researchers is that, in interview studies, little that is new comes out of transcripts after you have interviewed 20 or so people" The topic was also relatively focused - thus all the participants were drawn from a group receiving similar training, and were asked the same or similar questions,

based on the application of an *a priori* template. The number of statements obtained from the OHCPS in Scotland and Oman were approximately equal.

This approach ensured that the assumption of saturation was satisfied through the homogeneity of the participants, the content and structure of the interviews (Guest et al., 2006) and the specified cultural contexts (Romney et al., 1986).

4.2.3 Ethics

Because this researched involved human subjects, specific ethical approval was obtained in advance from the Medical, Veterinary and Life Sciences (MVLS) ethics committee of the University of Glasgow (Appendix 4.1). For the participants in Oman, ethical approval from the Research and Ethical Review & Approval Committee (RERAC) for the Ministry of Health Oman was deemed to not be required for this small set of pilot interviews (Appendix 4.2). Ethical approval was also obtained from the West of Scotland Research Ethics Service (Appendix 4.3). After reading an information sheet (Appendix 4.4), all of the participants in this study provided their informed written consent (Appendix 4.5). The participants' rights to anonymity and confidentiality were respected. Data were secured stored and processed in accordance with the data security protocol of the Community Oral Health Unit (available on request). The OHCPs are referred to only by code names and the identity of their practices is not revealed. The researcher reports no conflicts of interest.

4.3 Data Analysis

One important consideration in this type of research is whether to use computer assisted qualitative data analysis software (CAQDAS) such as QSR Nvivo (Richards.L, 1999).

This is relatively widely used, and allows for researchers to manage large amounts of qualitative data such as transcripts, notes or videos, and create codes for analysis (Bringer et al., 2004). However, there are strong criticisms of its use for the analysis of interview transcripts in health care research.

CAQDAS can involve too many mechanistic and rigid processes, and puts pressure on the researcher to focus on volume and breadth, rather than on depth of meaning (St. John and Johnson, 2000). The use of CAQDAS also reportedly results in the researcher exceeding the limits of the valid conclusions that can be drawn from qualitative data, for example,

through the coding of an excessive number of themes that may have limited meaning (Shönfelder, 2011). CAQDAS is also said to encourage researchers to collect and analyse very large cumbersome data sets, in excess of the amount of data required to achieve thematic saturation (Pope et al., 2000). Further, Zamawe points out that CAQDAS does not add to the scientific value of qualitative research, rather just makes data handling easier: "The main function of CAQDAS is not necessarily to analyse data, but rather to aid the analysis process, which the researcher must always remain in control of…no software can analyse qualitative data. NVivo and all other CAQDAS are basically only data management packages" (Zamawe, 2015).

In the context of qualitative research in dentistry, Burnard et al. (2008) and Stewart et al. (2008) also highlighted that CAQDAS does not replace the researcher's need to become fully immersed in the data. Thus, on balance it was decided not to employ dedicated software, but rather to manage the organisation and coding of data using Microsoft Word and Excel files drawn from interview transcripts.

In order to extract in-depth meanings from the interview transcripts the researcher made sense of the data by personally exploring, manually extracting, and interpreting significant statements to identify the themes. The first stage of the data analysis involved identifying clusters of statements among the interview transcripts that could be classified using a primary template based on a core of a priori themes extracted from the initial review of the literature and guidelines concerned with the early detection / screening for OCC (Al Bulushi et al., 2016).

4.3.1 Template Analysis

Template analysis, which is a widely used method for interpreting qualitative data in health care, business, and management research (Brooks et al., 2015; King, 2004; Waring & Wainright, 2008; King & Brookes, 2017) was applied to interpret the interview transcripts. The use of template analysis was in line with the aim of examining recommendations for the implementation of best practice by OHCPs, and / or to recommend future pilot study(s) into supporting preventive care. Whilst similar, thematic analysis (Braun and Clarke, 2006; Fereday and Muir-Cochrane, 2006; Clarke et al., 2015) tends to be more inductive (exploratory) and template analysis more deductive (confirming a template or thematic structure). The template analysis was underpinned by a) a core set of a priori themes (Table

1.5), and sub-themes extracted from the overview of systematic reviews and clinical guidelines; and b) the construction of theoretical connections between the a priori thematic areas, and behavioural and organisational themes in Capability, Opportunity, and Motivation derived from the COM-B model for identifying behavioural targets for possible intervention.

The priori themes were:

Theme 1: Conventional oral examination (COE)

Theme 2: Target population

Theme 3: Frequency of screening

Theme 4: Adjunct tools

The three stages of the data analysis involved: a) refining the initial template into a revised template, in response to the information provided and issues raised by the interviewed participants; b) identifying further clusters of statements that could be classified into emergent sub-themes by inductive interpretation; and c) making theoretical connections underpinned by the Capability, Opportunity, and Motivation (COM-B) model of behaviour, as defined in Table 4.1. Each of the themes were sub-divided into Enablers (i.e., capabilities, opportunities, or motivations that facilitated the early detection / screening of OCC) or Barriers (i.e., capabilities, opportunities, or motivations that hindered the early detection / screening of OCC).

Questions focus on the themes and probed for barriers / facilitators. A number of supplementary questions (Appendix 4.6) were asked about the specific issue of using a risk prediction tool (Conway et al., 2018) (INHANCE, 2018) and the feasibility of implementing such a tool in primary health care dental settings. Questions were designed to explore the views of the oral health care professionals on: benefits of having a tool for oral cancer that profiled / quantified risk using some patients information; the best way to utilize the tool in the practice; whether it might be used as a decision tool; if using the tool would help in introducing the term “oral cancer risk”; and how the professionals felt their colleagues would react to this tool and if they would be willing to use it.

The data analysis process was rigorous and required repeated contemplation and reflection for a period of over four months. This process was essential to make sense of the dataset, following Burnard et al. (2008) who, in the context of qualitative research in dentistry,

emphasized that "Analyzing and presenting qualitative data is one of the most confusing aspects of qualitative research" and "The process of qualitative data analysis is labor intensive and time consuming". All of the significant statements provided by OHCPs that could be classified into themes were transcribed line by line into the rows of an MS Excel spreadsheet. Each individual statement was manually coded with the ID code and status of the participant, and the statement number (e.g., S1 D1 referred to the first statement of dentist number 1 in Scotland). Each statement was initially classified within one of the a priori themes before refinement. All the themes in the secondary template were then connected according to how they reflected the facilitators / enablers and barriers associated with the Capability, Opportunity, and Motivation components within the COM-B model.

All the coded statements were aggregated into each constituent theme using the sort function of MS Excel, as described by Meyer and Avery (2009).

4.3.2 Authenticating the Qualitative Analysis

This type of interpretive research requires that the data analysis and subsequent results conform to the need for credibility, dependability, authenticity, and transferability (Denzin & Lincoln, 2008). Credibility was achieved through: a) the provision of evidence, in the form of a selection of significant statements, that were used to identify the themes; and (b) application of reflexive thinking to ensure that the results are believable and trustworthy. The researcher was aware of the need for reflexivity, meaning that in order to “negotiate the swamp” of qualitative data analysis (Finlay, 2002) she reflected personally upon what role she played in constructing knowledge, and tried to understand how and why she interpreted the data in such a way as to extract certain themes in preference to others (Johns, 2004; Johnson & Duberley, 2003; Day, 2012).

Because this research had a cross-cultural context, the researcher was also driven reflexively by cultural respect and awareness during analysis. As recommended by McCullough-Zander (2000) she did not work in conflict, but worked in conjunction with, the diverse belief systems related to the provision of health care that are inherent in different cultures. The researcher did not intentionally give preference to the statements of respondents whose opinions agreed with her own opinions, nor for example where answers matched consensus information provided in the literature or guidelines, as identified in the systematic overview.

Dependability was assured because the researcher provided sufficient methodological information for another researcher to repeat the data collection and analysis procedures and thereby obtain similar if not the same results. Authenticity was established by using an open process involving consented participation by the participants, promoting the participants' willingness to discuss their lived experiences and perceptions. Authenticity was also assured by the researcher seeking advice from the project team; there was close examination of assigning of statements during the analysis, and disagreements were discussed at length until consensus was achieved. Transferability of conclusions, i.e. how this study may inform and be applicable to other OHCPs working outside Scotland and Oman, is discussed in Chapter 6.

4.4 Results

The results are presented according to the four themes: conventional oral examination, target population, frequency of screening, and use of Adjunct Tools. Then, the structure of each theme is subdivided into: the prevalence of best practice behaviour(s) specified from Chapter 3; tabulated barriers and / or facilitators for optimal behaviour(s); and a short summary.

4.4.1 Participant Characteristics

In total there were 31 participants in this qualitative study (Oman n=18 and Scotland n=13). The characteristics of the participants are presented in Table 4.4. The majority of the participants from Oman were dentists (n=14), three of the participants were dental hygienists and there was one dental therapist. The most experienced participant had 24 years of experience and the least participant had three years. Five of the participants worked in Muscat city (Capital) and the remaining 13 worked outside the capital in the regional areas of Oman.

Similarly, in Scotland the majority of the participants were dentists (n=10, 3 males and 7 females). There were two dental hygienist / therapists and one dental hygienist. The longest experience was 36 years and the shortest was one month.

Table 4.2 Oral Health Care Professionals Characteristics (Oman and Scotland)

Oman				
ID	**Gender**	**Role**	**Years of Experience**	**Location**
O1	Female	Dentist	11	Capital
O2	Male	Dentist	3	Regional
O3	Male	Dentist	6	Regional
O4	Female	Dentist	3	Regional
O5	Female	Dentist	16	Capital
O6	Female	Dentist	3	Regional
O7	Male	Dentist	10	Regional
O8	Male	Dentist	24	Regional
ID	**Gender**	**Role**	**Years of Experience**	**Location**
O9	Male	Dentist	7	Regional
O10	Male	Dental Hygienist	20	Regional
O11	Female	Dental Therapist	5	Capital
O12	Male	Dental Hygienist	7	Regional
O13	Male	Dental Hygienist	21	Regional
O14	Male	Dentist	5	Regional
O15	Female	Dentist	4	Regional
O16	Female	Dentist	18	Regional
O17	Male	Dentist	13	Capital
O18	Male	Dentist	14	Capital
Scotland				
ID	**Gender**	**Role**	**Years of Experience**	**All Greater Glasgow and Clyde Health Board; Scottish Index of Multiple Deprivation (2016) Quintile** (1= most deprived, 5 = least deprived)
S1	Female	Dentist	36	1
S2	Female	Dentist	17	5
S3	Male	Dentist	31	5
S4	Male	Dentist	18	1
S5	Male	Dentist	33	2

S6	Female	Dentist	23	1
S7	Female	Dentist (VT)	1 month	2
S8	Female	Dentist	33	2
S9	Female	Dentist	16	2
S10	Female	Dental Hygienist	32	3
S11	Female	Hygienist/Therapist (VT)	2 months	5
S12	Female	Hygienist/Therapist (VT)	2 months	2
S13	Female	Dentist	14	1

4.4.2 Theme One: Conventional Oral Examination (COE)

Findings from the systematic overview (Chapter 3) recommended that the conventional oral examination should be performed for every dental patient on a routine basis, i.e. delivered opportunistically as an expected service in the primary care dental setting:

The COE should be delivered opportunistically, as part of routine primary care dental appointments.

4.4.2.1 Prevalence of Recommended Behaviour(s)

There was some variation in the description of examinations and it could be difficult to interpret how comprehensive they were, e.g. with respect to specific areas of the oral cavity, or to extra-oral aspects, but broadly the majority of participants in both countries described conducting conventional oral examination as recommended:

"You can look all over the oral cavity…the measure suspect areas, lips, tongue, sides of the tongue also, floor of the mouth, cheeks [...]" (O3)
"If somebody's open mouth immediately you will see the tongue and the borders and then, when you, check even the teeth you need to pull a little bit aside you need to pull the tongue. So, I check the teeth and I see the tongue, at the same time I see floor of the mouth. So, everything is done altogether." (S1)

"Extraoral just systematic - you just looking at the patient up above for symmetry then TMJ then extra facial tissues, bones, mouth opening, then you go intraoral soft and hard-buccal then mucosa palate tongue lateral ventral aspect, dorsal aspect of the tongue." (O10)

Although OHCP interview responses from both countries indicated the examination was broadly being done, there were some selective targeting (see next theme). Some (Oman) said they performed an extra-oral examination only according to need rather than routinely:

"Intra-oral examination, yes, or extra-oral whenever we feel that there is a need, but not routinely. Mirror, probe. We look at the gum, the teeth……the surrounding tissue, just a quick over…overview and…three in one tongue" (O6)

[So do you conduct…oral soft tissue examinations for all of those…patients?] "Not…not always" (O7).

4.4.3 Barriers and Facilitators

Table 4.4 shows the behavioural diagnostic coding for COE, i.e. barriers or otherwise to evidence-based practice.

Table 4.3 Behaviour model coding for COE with illustrative quotations

Coding	Description	Illustrations
C. Psy.	Generally good knowledge of lesions and abnormalities facilitates COE behaviours	"It is just standard and it is very easily to detect any oral cancer in every standard examination. We are prepared to do examination. We are detecting cancer and precancer…lesion and any suspicious lesions" (S1). "We are searching for any abnormalities…ulcers, resistance ulcer also…and after that we are going to… palpate… suspected. Everything you suspect you should check a lot" (O3).
C. Phys.	Some technical variation e.g. order of intra/extra oral examination	"Labial, buccal, retromolar, um, floor of mouth, base of tongue, anterior two thirds of tongue… Oropharynx, tonsillar, gingivae. And then, um, lymph nodes, posterior lymph nodes, internal jugular, sort of, high, medium and low…and then some mandibular submental […]" (S5) "[…] I sort of start from the… the chin below and… feel round their jawline […] so, do extraoral and then sort of look at their face to…to ensure that both sides are symmetrical, um, and then look for anything suspicious, um, and then do intraoral examination" (S11)
	Technical omission such as visual only, or internal only	"We do…we check but it's mainly a lymph node check and then a soft tissue examination. Just a visual examination" […] (S8). "General examination, like teeth, gums and buccal mucosa and tongue" (O2)
Op. Soc.	COE carried out but perception of patient worry might be an inhibiting factor – more so in Oman	"Um, I don't say I'm looking for oral cancer… because I think the word cancer scares people a lot. know some people say that you should use that term, but I just say that I'm checking all the tissues and making sure there's…that everything is looking healthy" (S7). [So basically, […] you will be doing the work, and without… panicking the patient?] "Yes, of course; that will make them freak out." (06).
	Mixed reports from Oman on social barriers with respect to gender of OHCP/	"Yes…some of the [female] patients they want a female dentist to examine them." (O2). "[You are a male dentist and you have a female patient, do you

Coding	Description	Illustrations
	patient	think there is any barriers?] "Well I don't face any trouble in this because, you know, in our religion, it's fine to be seen by a doctor, because it's for treatment." (O1)
Op. Phys.	Some reports in Scotland about time constraints inhibiting COE	"If you know, how long does it take you to do a full charting? […] To look at the soft tissues, to look round the head and neck? All these things and then to ask about…some patients it takes you ten minutes just to get through the [medical history] before you even look at these things." (S5). "The thing about it's an NHS practice and it's busy…and I know it's not an excuse but time restraints." (S10).
M. Ref.	Some motivation from previous detection	"Just check for lumps and bumps all over the skin […] I've certain seen, I've seen a couple of squamous cell carcinomas" (S5)
M. Auto.	Reports in Oman of COE not being within scope of professional practice/ role	"No, we don't do patient screening. This is usually done by the dentists and it is his work" (O11).

4.4.4 Theme Summary- COE

COE is reportedly being implemented in practice in both countries, with some qualifiers:

- Participants broadly reported screening patients, but some barriers were outlined
- However, in Scotland time and resources issues were the strong barriers
- In Oman, lack of training (and a perception from hygienists that only the dentist should perform COE) emerged as barriers
- Most were happy to relate the screening to cancer. One exception in Scotland felt this was 'scary' (a social opportunity barrier) but this 'cancer taboo' barrier was stronger in Oman (see next chapter for the patient perspective)
- Reports of other cultural barriers in Oman were by no means homogenous, but as might be expected there were some sensitivities, for example for a male dentist examining a female patient

4.5 Theme Two: Target Population

Chapter 3 shows some equivocal evidence in terms of targeting, but concludes in summarizing the systematic overview that:

- COE should be conducted opportunistically for all (i.e. the general public)
- Risk status should be ascertained through smoking and alcohol history

4.5.1 Prevalence of Recommended Behaviour(s)

Seven of the OHCPs in Scotland (S1, S2, S4, S5, S7, S9 and S10) clearly reported early detection / screening detection of OCC through universal conventional oral examination among the general patient population (emphasis in bold / underline added), for example:

"Everybody has to be… checked because we know… that… risk of a cancer could… affect everybody so we need to **treat everybody in the same way**." (S1).

"Generally look at as much as we possibly can, **for everybody**." (S4).

"Yes, **every single patient**, yes, soft tissue exam…either nothing or anything that I'm aware of I will write it down and I will bring it to the attention of the dentist straightaway." (S10)

However, four of the OHCPs in Scotland (S1, S6, S8, S11) reported targeting - that is that they mainly employed early detection via conventional oral examination and soft-tissue charting among the high-risk population, for example:

"**Especially elderly people** it doesn't matter what is the gender who have diabetes, high blood pressure, problem with circulation and. arterial sclerosis, heart disease…also taking some sort of medications, which affect circulation in the small blood vessels, can be in the higher risk of the cancer" (S1).

"**Especially with** maybe older people and denture patients." (S6).

"It's for all the **patients over 30**." (S8).

"**I particularly check smokers**…So right at the back normally here is where sort of smokers' keratosis and the ridges, and things." (S11)

The picture in Oman was similar in that seven of the OHCPs in Oman (O1, O2, O3, Q4,07, O9 and O10) reported early detection / screening of OCC through conventional oral examination for the general patient population, for example:

"Mostly we do a detailed examination **for each patient."** (O2 D).

"General examination for **all appointed patients**." (O10).

However again there were reports of targeting to the higher risk population, for example:

"[So, if your patient, for example, has a risk factor, he's a smoker, he's an alcohol drinker, then you tend to do the, the **screening only in those patients**]? **Exactly**." (08)

4.5.2 Barriers and Facilitators

Table 4.5 shows the behavioural diagnostic coding for targeting based on risk, i.e. barriers or otherwise to evidence-based practice.

Table 4.4 Behaviour model coding for target population with illustrative quotations

Coding	Description	Illustrations
No coding for capability or social opportunity		
Op. Phys.	Training / guidance / protocol facilitates good practice	"Well, the…the guideline when we were training was to do it for everybody at examination […] (S9). "[Is it a protocol you have to do this for every patient]? Yes- it's a protocol. Even intraoral or extraoral." (O3).
	Lack of local written guideline is a potential barrier	"I'm just following, like… the basic guidelines, which is, like… routinely checking up. [Okay, but you don't have anything written in the clinic?] No." (O8).
	Resources issues favour targeting (i.e. are a barrier to universal examination)	"Under the current…system of remuneration I think… that's difficult… the amount of things that we're being asked to look at as well as…so there's oral cancer. Then there's tooth wear. There's tooth erosion… bruxing…clicking jaws…temporomandibular joints, dah, dah, dah, dah. So the…amount of stuff we're meant to record at an examination… is quite large and I think …it would be difficult to get you to carry that on every patient, at every exam." (S3). "Em, it comes down to time and money…Eh, and constantly every time something else comes out you're adding onto it, but funding doesn't increase in any way, shape or form… and you can set all the guidelines in the world, but people won't do it if...em, if there's no way of funding it…" (S4).
M. Ref.	Targeted screening was reasoned on smoking risk (can be interpreted s a barrier to universal checks)	"I particularly check smokers…So right at the back normally here is where sort of smokers' keratosis and the ridges, and things." (S11)
M. Auto.	General point about the position/ professional role of dentists with regards to early detection	"A huge advantage about dentists is we get the healthy people, so we're getting them before they've developed disease." (S5).

4.5.3 Theme Summary- Target Population

The varying reports among OHCPs on targeting perhaps reflect the results of Chapter 3, where evidence was unclear and guidance was varied as to whether targeting those at risk is recommended (i.e. some guidelines recommend screening of high risk patients and some recommend patients above 40+, though the majority suggest universal screening as part of a routine dental check-up):

- Responses across countries were very similar - mostly general public screening with some targeting, mainly on age and smoking
- Guidance / protocols did emerge as a facilitator for carrying out COE for all
- Universal detection / screening efforts bring a resource consideration which was mentioned in Scotland

4.6 Theme Three: Frequency of Screening

There was a limited evidence base for a differential in the frequency of oral cancer screening /early detection based on risk in the systematic review. In practice, convention is to carry out checks every six months for all. One high quality guideline (NICE, 2004a) recommended that frequency of recall should be based on patient risk (i.e. smoker or alcohol drinker) with a suggested recall interval of 3-6 months for high risk and 12-24 months for lower risk:

- There is no strong evidence but some guidance recommends risk-based recall intervals (shorter for high risk patients)

4.6.1 Prevalence of Recommended Behaviours

Recall intervals for routine checks were reportedly almost always universal i.e. the same for all patients. There was some reluctance to reducing checks (increasing time between screens) in that 'low' risk patients might not receive optimal care (see Table 4.6):

"But given that we look at everybody I don't know are we going to look different because they come out at high risk? Am I going to not look as carefully because they're a low risk?" (S8).

Most recall discussions in Scotland focused on what we might term 'follow up' – i.e. reactive to something like a lesion or abnormality being observed (rather than proactive checks based on risk per se):

"If I identify a thing that I don't know what it I'll get them back in …two weeks' time to see if it's resolving." (S2).

"If it looks atypical… then I would book them back in and I would… want to see them in… two or three weeks." (S5).

Similarly in Oman, checks were not more frequent based on risk factors, but if lesions were picked up. Here they are referred straight away (rather than patients being brought back to the OHCP for follow-up):

"What we normally do is, we refer and they are being followed up at the tertiary centre. We don't follow them up. Er, well, they, they may come for other [things], you know, [such as] for filling or scaling, but they…for the white lesion, they are being followed up in the…for the lesion particularly, and they may follow it up in the tertiary." (O6).

4.6.2 Barriers and Facilitators

Table 4.6 shows the behavioural diagnostic coding for recall frequency based on risk, i.e. barriers or otherwise to evidence-based practice.

Table 4.5 Behaviour model coding for frequency of screening with illustrative quotations

Coding	Description	Illustrations
No coding for capability		
Op.Soc.	Patients risk perception may be a barrier to shorter recall intervals	"The trouble is the patient doesn't always come back so… that's a…a problem. They don't always accept that it's a serious enough thing." (S9).
Op. Phys.	Structure of practice is based on regular checks for all	"Statement of Dental Remuneration and the … Practitioner Services and Scottish Dental Practice Board, they make all the rules and we have to follow them and obviously show that we're doing care for patients." (S7).
	Resource issues drive/ facilitate risk-based recall	"Well, in my opinion, let us [bring] in those kinds of people who are with high risk… Yeah. Because of time, saving time, and for so many…" (O13). " …I think the main thing with dentistry is…it needs to be kind of easy to access…because you don't have a lot of time with each patient in the NHS dentistry, so…but this [assessing risk] would be quite helpful, yeah." (S7).

Coding	Description	Illustrations
	Lack of guidance emerged in Oman	"I don't have any protocol here. [No guidelines?] We didn't [You don't follow any?] No." (O2). "We don't have, here, something like…something will guide us." (O4).
	Risk tools (see below) could be a resource to facilitate risk-based examinations	"Okay. And…and I think this…the [risk assessment] tool could be used as a decision tool for clinical examination […]" (S3).
M. Ref.	In Scotland, some reflection on the unintended effect of missed detection for 'low risk' patients	"…I just…my worry would be…we'd miss…yeah. Uh-huh…And, um, you know, I'm…I'm sure oral cancer must develop in some low patients as well as the high risks, you know." (S2).
No coding for automatic motivation		

4.6.3 Theme Summary- Recall Frequency

Recall was reportedly universal at twice yearly. This is broadly what the evidence review currently supports, though guidance suggests a risk-targeted approach:

- Responses across countries were very similar - but in Scotland patients were recalled for further observation when abnormality observed, and in Oman referred in the first instance
- Frequent recall for high risk patients was supported, but a barrier emerged in terms of resources, and in terms of patients not attending check ups
- Less frequent recall for low risk patients was less well received – the barrier being the view that they might be at risk from later detection
- Lack of clinical guidelines in Oman was a barrier as it was reported OHCPs had no guideline to follow

4.7 Theme Four: Use of Adjunct Tools

The systematic overview shows a lack of supporting evidence for the use of Adjunct Tools alongside the conventional oral examination for detecting OCC and OPMD in the primary care dental setting:

- Adjunct tools not recommended in Primary Care

4.7.1 Prevalence of Recommended Behaviour(s)

Only two of the OHCPs in Scotland and none of the OHCPs in Oman reported that they used Adjunct Tools (e.g., stains, fluorescents), though most were aware of them:

"Do you use any agent tools to identify a lesion?] No [So do you think…is it feasible to use in your practice] Yeah. Oh yeah, definitely. I'm aware that we could do it in the practice." (S2).

"I've heard of them but no, no, I don't do anything like that. I don't know that we have the equipment. I've never been provided with them in any practice." (S9)

"No, they're not using it." (O8).

As their use is not currently recommended in the Primary Care dental setting, this might be said to be 'evidence-based practice'. However, it is still interesting to explore the reasons given for use / not use**.**

4.7.2 Barriers and Facilitators

Table 4.6 shows the behavioural diagnostic coding for Adjunct Tools for screening.

Table 4.6 Behaviour model coding for Adjunct Tools with illustrative quotations

Coding	Description	Illustrations
C. Psy.	Some allusion to not being technically skilled/ trained	"I would very much rather refer to somebody who was... more specialised than me rather than, you know, doing... that kind of slightly more advanced testing […]" (S4).
No social opportunity coding		
Op. Phys.	In Scotland, training would be a facilitator in terms of resource opportunity	"…I've heard of them but [...] I would obviously want to…to think about maybe having some training before I was to…to do anything like that..." (S9). "Using things like visual tools for the patient would be really good as well on top […] because we don't use that in current practice […]" (S11).
	Resource/ time barriers	"I try to introduce in another practice but you have to pay for better tool…you have to pay for the test NHS… doesn't cover additional examination. The test altogether takes around twenty minutes to do it properly and… also we use the white light to highlight the toluidine blue…this test takes between twenty to thirty minutes." (S1).
	In Oman, non-use attributed mainly to lack of provision of tools	"No, we don't use it. [because] It's not provided."(O1). "No, we have lack of these tools." (O3)

Coding	Description	Illustrations
	Some reflection in the other direction – a facilitator for usage	"[Do you use any tools?] I feel like it would be probably really beneficial because like oral cancer can be quite aggressive as well and, um, like if you're finding that sort of middle like stage like patients' chances of surviving is dramatically reduced. Um, I feel anything, because it's the patient's life at the end of the day, anything that can help prevent the loss of life would be massively beneficial in practice." (S11). "[What might improve things?] So yeah, erm, something a little bit more specific, and maybe even the staining, erm, whether that might be, you know, to use different dyes for staining, erm, again might be a good idea in, in detecting and maybe moving forward….I'll certainly have a look at these and I will speak to the dentist regarding these dyes." (S10).
No coding for automatic motivation		

4.7.3 Theme Four Summary

Whilst Adjunct Tools are not well supported by evidence (Chapter 3) and not observed in practice here, there are still what we might call 'barriers' to implementation. In Oman lack of provision of tools was cited for non-use, and time and resources (including training needs) were cited in Scotland. This might tentatively be inferred as "doing the right thing for the wrong reason'(this might actually be 'coded' in terms of lack of knowledge-capability issues re evidence-based dentistry in relation to the use of Adjunct Tools):

- Rather than reflecting on evidence, the OHCPs in Oman overwhelmingly attributed physical opportunity barriers such as unavailability of resources for not using such Adjunct Tools in screening patients for oral cancer
- In Scotland time and resource issues for carrying out such screening were mentioned (although some had researched the evidence)

4.8 Risk Prediction / Assessment tools

Themes two and three cover targeting and recall based on risk. OHCPs were specifically asked about risk assessment in practice and the acceptability / feasibility of using a risk prediction tool for identifying those at high risk of oral cancer; a prototype tool developed by the INHANCE network (INHANCE, 2018) was used to facilitate discussions.

The majority of professionals broadly welcomed the idea of using such a risk tool:

"If it is approved risk factor assessment then yes. As this will be like a guideline for us to use it." (O1).

"I think generally positive, I would imagine…Erm, yes, it's hard to say. Everybody has very different opinions [laugh] but…I think, you know, most dentists want to make sure that they're helping patients, that they're detecting things early." (S9).

Barriers were mainly resource (physical opportunity) based and are again tabulated.

Table 4.7 Behaviour model coding for risk assessment tools with illustrative quotations

Coding	Description	Illustrations
No psychological capability coded		
C.Phys.	Technical question about reliability of administering tools	"[It] can cause confusion because if a nurse does it in a different way with each dentist on different days, that's how mistakes happen." (S5). "Um, in…at the end of the day, the only thing you've actually got is…is the quality of, er, the person doing the assessment. (S5).
Op.Soc.	Social barrier for patients answering risk questions (use of waiting room as a facilitator)	"I prefer they do it in the waiting area….[why]… I think on their own they may be true to themselves… They might be more honest. Whereas, when you're faced with questions, you may not want to answer, or give the entire truth, to someone else as an answer. You don't want them to look down on you." (O17). "Well unless I try it on a few patients and see their results I cannot judge." (O18).
	Social barrier in explicitly raising cancer risk	". I don't know if it could alarm patients. I don't know how that would…maybe that brings about change. I'm not…I'm not sure. Um, but I think that if you were using a tool like this, it…definitely highlights in the patient, why are they talking about this? You know, this is obviously important." (S2). "because the minute you say…cancer, patients get really nervous, um, and they do get nervous if you say you've seen something in their mouth, so you have to just be very diplomatic, you don't want to nu…worry them, but you obviously want to tell them what you've seen…So yeah, I think that's probably quite a good idea." (S7).
Op. Phys.	Time to assess risk is a barrier	"Time as I mentioned we have only 30 minutes for each patient and the majority of the patients come in for treatment not for consultations. So, if I ask them to conduct this that will take at least how many minutes? Twenty minutes, fifteen minutes to finish it"." (O18) "Em, there's only so much time you can allot to it. So, eh, if you've got an admin process and a clinical process. Em, you know…How...how do you allot the time, eh…that you're compressing more and more things into the...same time, eh." (S4). "...That is the sort of thing that you probably need to increase your appointment time for, isn't it?...Because it already takes them five

Coding	Description	Illustrations
		or six minutes to fill up the medical questionnaire." (S8). "Em...It's, em, it's...it's very nice in theory. In practice, eh, not so simple. Em, you know, you're...you're talking about, eh, hundreds if not thousands of patients in a week...eh, that are trying to...to fill all these things out. Em, if somebody is willing to fund us to have, you know, a couple of hundred tablets so that...if you happen to have lots of people there and...they walk out with one and, you know, everything else that's...that's good. Em, but I think that the...the feasibility of that is...is quite low." (S4).
	Building routine would be a facilitator, as would technical delivery	"Um, I think again it would just…as long as it's not going to eat into too much time…I think you can still do a very thorough examination and not spend too much time on it, um, if you're doing it properly, so if you just make it part of your routine." (S7). "It could be app, er, like, er…er, of, er, are you risk of cancer, check yourself…Yeah, er, yeah, set of questions could be, er, but, er, yeah, maybe it will be good. Maybe it will be good. And then he can do self, er, for example, people on…on their mobile phones are looking for apps." (S1).
	Most professionals in Scotland saw resource barriers with regards to software as this would require an electronic link to the patient management system:	"It would need to be paper I think…because we don't have a computer sitting." (S8). "If it was incorporated in to R4 would be really helpful." (S2). "I mean and…and certainly something electronic but I mean most practices are computerised now, not everybody…but…and, er, quite a number of practices, and we're looking to do this as well, I know the doctors do this, have, erm, you fill in your medical history on a tablet." (S3).
M. Ref.	Reasoning that accuracy improved by direct administration	"I think face to face is much better. At least I would have the correct and real information from the patient directly. If I talk to him face to face and then fill it directly, step by step, that will help more." (O18).
No automatic motivation coded		

4.8.1 Risk Tool Summary

Overall, the risk prediction tool could be said to be broadly considered worth exploring, but with feasibility concerns regarding resource (physical opportunity) barriers. There was an additional social barrier with the issue of whether patients would be rendered upset by introducing cancer risk explicitly:

- Broadly welcomed but some social barriers with patients, in both countries.
- Time, money, training etc. would need to be taken into consideration by the tool developers in order ensure that product might be implemented with few or no obstacles to enhance care.

- Waiting room completion by patients (i.e. questions not administered directly) might overcome time barriers, but dentists would worry about accuracy of data.

4.9 Discussion

Four themes defined by the primary template in Table 4.1 (i.e., conventional oral examination, target population, frequency of screening, Adjunct Tools) were explored in this qualitative study from the practitioners' perspective, together with their views on risk assessment tools.

The results were broadly consistent with the findings of the systematic review and the presence or absent of evidence across the themed areas. However, the reported results, based on these themes, indicate that not all the best practice evidence and guidelines are currently implemented by OHCPs in either Scotland or Oman. This backs up previous work showing variation in practice (LeHew et al., 2010) and issues following and implementing guidelines (Ayres and Paas, 2007).

Comprehensive examinations were partially in evidence, but some descriptions of activity were vague and there were some gaps. Under COE, the structured examination including intra- and extra-oral aspects and, e.g. pulling the tongue, is well addressed in dental health care education in various levels (Uti et al., 2006, Seoane et al., 2012) but descriptions in this study were varied and could be difficult to decipher.

There were wide variations among the OHCPs in both Scotland and Oman regarding the specific criteria that they applied to focus their early detection / screening for OCC on high risk patients. We know there are knowledge gaps in GDPs' awareness which probably drive different opinions on screening per se, and how effective it can be for reducing mortality and morbidity (Kujan et al., 2006).

Criteria for targeting included elderly patients, patients over 40, patients with high blood pressure, problems with circulation, arterial sclerosis, and heart disease, as well as denture patients, smokers, and alcohol drinkers. The need to identify more specific criteria in order to identify high risk patient needs further evaluation. Cognitive capabilities were different between Scotland and Oman, because in Oman the OHCPs appeared to have little or no knowledge or understanding of written guidelines such as those provided to the OHCPs in Scotland by the Practitioner Services and Scottish Dental Practice Board (SIGN, 2006, SDPB, 2010).

Recall was interesting in that practitioners mainly described follow-up (e.g. after observing a lesion). However, broadly, they had comparable intervals for all patients whether high or low risk. This is in line with current Cochrane evidence although guidance suggests this worthy of continuing exploration. OHCPs on balance were more wary of longer intervals for low risk patients (as might be expected) but there were resources issues raised for more frequent checks / shorter time intervals for high risk patients (National Institute for Clinical Excellence, 2004)

Use of Adjunct Tools was limited in OHCPs in both Scotland and Oman. Omani reasons were more simply about opportunity / availability, whereas there was some more reflection and reasoning in Scotland. However, in Scotland time and resource issues, including training, were raised. It is known from Chapter 3 that visual-based techniques lack strong evidence (Messadi, 2013) despite some small studies indicating promise (Richards, 2010), and there might still be utility in raising knowledge / awareness in this regard.

This research was partly driven by the researcher's personal perspective of being influenced by more than one culture, which reflects a large population of clinical oral health professionals with experience of working and /or studying in both Western and Arab cultures (Aboul-Enein and Ahoul-Enein, 2010). Differences in practice were not perhaps as large as one might expect given the socio-political and cultural setting in each part of this study. But this may in part be due to the high proportion of Omani practitioners who studied or obtained qualifications abroad.

Broadly, efforts in Oman are needed to help relieve the restrictions on social opportunities for OHCPs to conduct early detection / screening of OCC associated with (a) religious / cultural beliefs regarding the treatment of female patients by male dentists, and (b) the psycho-social barrier of talking about oral cancer. Future work could explore further the wider cultural landscape affecting all health and social care interactions. For example, this research was not concerned directly with identifying cultural stereotypes, reflecting unique patterns of behaviour and belief, that characterize specified groups of people in different nations.

In Scotland, time, cost, and lack of resources were the main limiting factors for routine screening / early detection efforts overall. Such barriers related to spending time explaining the risk to individuals has been previously indicated in a study carried out in general

practice by (Steenkiste et al., 2004). This was the main sphere for barriers to use of risk assessment / prediction tools which were broadly seen as worthy of further exploration.

4.9.1 Strengths and Limitations

The significance of this study lies in the attempt to relate practice (work as done) to evidence / guidance (work as dictated or planned; Clay-Williams and Braithwaite, 2016).

The use of a flexible theory-based framework ensured coverage of the potential barriers and facilitators affecting behaviours under each theme which together make up the behavioural domain of the early detection / screening of OCC.

The theoretical frame was useful and important to show coverage of barriers. The components of the COM-B model (Mitchie et al., 2011) are applicable to this area of practice; physical / psychological capabilities (skills and knowledge) and physical opportunities (time and resources) in particular interact to enable the early detection / screening of OCC. The descriptions of the physical capabilities of the OCHPs in Scotland and Oman when conducting conventional oral examination and soft tissue charting, and capabilities in taking biopsies, appeared to be similar.

Results indicated that social opportunities for OHCPs to conduct early detection / screening of OCC in Oman may be more restricted than in Scotland, due to: (a) religious / cultural beliefs regarding the treatment of female patients by male dentists, and (b) the psycho-social barrier of talking about cancer (Bertakis, 2009, Henderson and Weisman, 2001), however within the scope of the study, it was not possible to delve deeply into the wider social / cultural issues.

The generalisations that can be drawn from the analysis of qualitative research data obtained from a purposive sample are limited by the thematic results being a reconstruction of the subjective experiences and perceptions of a small number of participants, working in specific situations and locations (Mayring, 2007). Other OHCPs in different situations and locations could have provided different information to that provided by the OHCPs who participated in this study. Whilst some attempt was made during sampling to ensure a spread of responses and through numbers to achieve some data saturation, the findings of this study are not necessarily generalizable to the OHCP population as a whole.

The researcher did not intentionally eliminate any statements that were directly opposed to her own personal opinions, or information provided in the systematic reviews or clinical guidelines. Nevertheless, despite attempting to maintain a neutral stance, the researcher recognised that, like all observers, she has subjective prejudices. Her subjective judgments and personal ideas relating to the need for OHCPs to implement improved methods of detecting, screening and preventing OCC might possibly bias some of the results and conclusions.

4.9.2 Conclusions and Recommendations

The knowledge gaps indicate that guidance could be targeted for intervention (see Chapter 6). Future research is required, based on the findings of the current study, to establish which written guidelines could be built into a future pilot intervention to support the early detection of oral cancer in general dental practice. This issue is particularly important for the OHCPs in Oman, where such guidelines appear to be absent (there is patient management software (Al-Shifa: Health care Information System) (MOH, 2019 and Al Ghabri et al., 2014) which provides for documenting COE results but this is underutilised.

In Oman, guidance is lacking and facilitation through this means is likely to have an effect. These new guidelines should include: a) descriptions of best practice to conduct COE and soft tissue charting, including discussion around the use of Adjunct Tools; b) the specific criteria applied to focus attention on the early detection /screening for OCC among high risk patients; c) the optimum time interval to recall patients with suspected OCC; d) the best pathways for the referral of patients to specialists, and for the receipt of feedback.

Future implementation could potentially employ Quality Improvement (QI) principles such as the Plan-Do-Study-Act (PDSA) cycle, thus incorporating a built-in evaluation process. The PDSA cycle is widely applied to evaluate the effectiveness of health promotion and QI programmes (Healey & Zimmerman, 2010). A PDSA approach here might be fruitful in: reviewing related procedural standards / up-to-date evidence for clarity in the practices discussed here; co-designing improvement with OHCPs; taking into account the restraints of cost, time, and other resources; designing workshops and / or training programmes; etc. Routine methods such as the collection of audit or self-report data might allow for summative assessment on improved evidence-based practice (Dimitrov & Rumrill, 2003).

The next chapter now builds on these results by exploring patient experience and views in relation to oral cancer early detection / screening in a further exploration designed to overcomes the barriers related to implementation of the synthesised evidence base (Chapter 3) in relation to the early detection of mouth cancer.

Chapter 5: Patient views on early detection / screening for OCC in dental settings in the Sultanate of Oman and Scotland

5.1 Introduction

This chapter builds upon the overview of evidence-based practice (Chapter 3) and the theory-based exploration of the professional perspective in Chapter 4 to incorporate patient views in relation to oral cavity cancer early detection / screening, by describing a qualitative study which was conducted with a sample of adult patients attending primary care dental settings in both Oman and Scotland. The main aim was to provide data for a final synthesis of the evidence base with perspectives of professionals and patients alike in this area; a further aim was to make a comparison between the two countries.

It has been reported previous that patients may lack general knowledge of oral cancer and be unable to recognise symptoms (Ford and Farah, 2013).

Involving patients' views in the development of clinical guidelines and their decision-making in treatment plans have potential for improving the quality of health care and treatment outcome; this is through meeting patients' needs and preferences (Loh et al., 2007; Gagliardi et al., 2011; Kastner et al., 2015; Armstrong et al., 2018). Although existing recommendations (e.g. NICE) support the patient's involvement in their treatment plan of care, there is limited evidence to conclude that patient involvement in health care system decision-making helps to improve health outcomes and service utilization (Joosten et al., 2008; Shay and Lafata, 2014; Boss et al., 2015; Friedrichs et al., 2016; Kashaf, McGill, and Berger, 2017). Nonetheless, patient involvement has been shown to help them to improve their knowledge and decision-making related to their treatment (Joosten et al., 2008; Shay and Lafata, 2014; Boss et al., 2015; Friedrichs et al., 2016; Kashaf, McGill, and Berger, 2017).

In relation to oral cancer screening, previous studies (chapter 1) have looked at patient views on oral cancer screening in dental settings (Warnakulasuriya et al., 1999; West et al.,

2006; Zohoori et al., 2012). However, little or no work has looked at different cultures / countries, and there is a patchy picture with respect to the application of psychological / behavioural theory in designing research questions.

5.2 Aims and Objectives

This study accordingly aimed to explore the following research questions:

a) What are patients' experiences of previous and current OCC prevention within primary care dental settings?
b) What are patients' levels of awareness and understanding in relation to OCC?
c) How do patient views provide barriers / facilitators to practitioners implementing OCC early detection / screening?
d) What are the patients' suggestions in relation to the development of interventions for improving OCC early detection / screening, including use of risk prediction tools for targeted prevention?

In order to answer these questions this study had the following objectives:

1. To gain ethical approval from research institutions in relation to this study from both countries
2. To recruit patients in both settings. This study involved targeted recruitment of patients attending practice
3. To collect data via a semi-structured interview guide incorporating open-ended and fixed response questions
4. To analyse the data using psychological theory
5. To report the findings and discuss them in relation to the evidence-base and dentists' views

5.3 Method

The theoretical frame is described in Chapter 4. Patient responses were coded in terms of the TDF and COM-B frameworks (Cane et al., 2012) and assessed for whether they presented barriers or helped to facilitate the desired screening behaviour of professionals. The design chosen for this study was a 'mixed-method' questionnaire incorporating both open (free response) and closed (fixed answer) questions (Boynton and Greenhalgh, 2004). The selected questionnaire type was incorporated primarily for practical reasons – interviews were necessarily short, being conducted during dental visits. Qualitative / open-ended questioning was thus supplemented with some time-saving fixed-response questions - also used in an exploratory fashion to gain general views on acceptability and feasibility.

5.3.1 Participants

Participants were adult patients attending dental primary care settings in both countries. Participants were English-speaking adults in Scotland, and Arabic and English speakers in Oman. A total of 48 patients were interviewed, n=24 in each country. Recruitment was facilitated via contacting primary care clinics who gave access to facilities for interviews and permission to approach patients arriving on the fieldwork days who were then consented by the researcher according to the ethical protocol.

5.3.2 Designing the Topic Guide

For the semi-structured interview, a topic guide was developed with the research team of psychologists and dental and public health professionals. Topic guides are a key tool in facilitating data collection as they ensure the interviewer covers pre-set questions but allows for this to be done in a flexible way. In this study, the research followed the Interview Protocol Refinement (IPR) framework (Castillo-Montoya, 2016). This framework consists of four stages: 1) Align interview question with research questions, 2) Construct an inquiry-based conversation, 3) Receive feedback on interview protocols, 4) Pilot the interview protocol.

Stage 1: Interview question align with research question

This stage involved alignment of research questions on oral cancer screening with questions to ask patients. As there was no pre-existing interview question-set available from the literature, questions were developed based on study aims, the narrative synthesis of evidence (Chapter 3), and from findings from professional interviews (Chapter 4).

Stage 2: Construct an inquiry-based conversation

It is important under IPR that questions do not treat participants as solely being vehicles for extracting answers to research questions – but are also designed to allow them to express their lived experience - in this case of attending dental clinics. This inquiry-based conversation is achieved through: a) tailoring language of questions to interview ones rather than formal research ones; b) following social rules of ordinary conversation so that questions are fairly naturalistic; c) having a variety of questions / ways to probe; d) having a hierarchy with general topic questions and follow-up / prompt questions to be used where appropriate or necessary (Appendix 5.1). In this study, there was also the consideration of

language - for example ensuring that the Arabic translation of the clinical guidelines was in everyday language that could be understood by the patients.

Stage 3: Receiving feedback on interview protocols

The researcher received feedback on the topic guide structure, length and the writing style from the advisory group of experts in behavioural science, dental public health and oral medicine who contributed to the development of the survey instrument. This stage was very important to enhance the validity and robustness of the study guide.

Stage 4: Piloting the interview protocol

In stage 4, practice interviews (and training) were conducted with patient volunteers in Scotland in the presence of two supervisors (AJR and DIC) in order to further develop / fine-tune the topic guide in response to any difficulties or omissions and to give the researcher practice in interview technique. One of the pilot 'patients' was a 'smoker and regular alcohol drinker', while the other was a 'non-smoker and occasional alcohol drinker'; one of the participants was 50-60 years old, and the second between 20-30 years. Subsequent reflections and feedback from the pilot participants and supervisors prompted some changes to the survey instrument. For example, the sequencing of the interview questions was changed (for example, having a risk score first, and then categorisation option of traffic light or percentage). Generally, however, it was felt that the questions were acceptable and relevant to patients attending dental practices in Scotland. No major changes were required following the pilot. In Oman, the questions were used in both languages (Arabic and English), the questions were checked with a few relatives (medical professionals) and no major changes were required.

5.3.3 Recruiting the Sample

As in the study reported in Chapter 4, purposive sampling (Ritchie, 2014) was employed in order to capture a range of views from people that could inform the research aims – i.e. adult patients attending a dental clinic. Smaller sample sizes are typically used for qualitative studies as the aim is not to make statistical inferences to the wider population (Ritchie et al., 2003) but to provide a rich detail to inform development of more definitive studies. Practically, data saturation (no new themes or experiences emerging) is achievable without large samples - which would be prohibitively time consuming to collect and analyse - and which would lead to high levels of repetition (Guest et al., 2006; Ritchie,

2014). For qualitative studies, sample sizes of between 12-60 are recommended (Creswell, 1998; Ritchie, Lewis and Elam, 2003) but saturation can be achieved earlier in some cases.

In the present study, the author aimed to recruit 24 dental patients attending primary care dental settings in each country, subject to reaching saturation.

5.3.4 Analysis

The data for this study were analysed thematically (Braun and Clarke, 2006) guided by the linked theoretical frameworks of the TDF and COM-B models described in the previous chapter for patient barriers (Atkins and Michie, 2015).

Analysis first set out current practice from the patient perspective – i.e. answers to questions on previous experiences with oral cavity examination (e.g. did / does the dentist retract your cheek, did / does dentist pull your lower lip to check the inner side of your lip, did / does dentist use gauze to grasp the lip of your tongue and look at the back and the side of the tongue?). Responses were thematically coded according to the TDF domains and COM-B components and assessed as barriers or facilitators to recommended practice.

5.3.5 Ethical Considerations

For the purpose of fulfilling ethical requirements for this qualitative study, formal approvals were obtained from the two countries. In Oman, the approval was granted from the ethics committee of the School of Medicine, Dentistry and Nursing at the University of Glasgow (Appendix 5.2), and the Research and Ethical Review & Approve Committee (RERAC) for the Ministry of Health in the Sultanate of Oman (Appendix 5.3). In Scotland, the ethical approval was obtained from the National Health Service (NHS) Research Ethics Committee (REC) (Appendix 5.4), and the NHS Greater Glasgow & Clyde Research & Development (R&D) department (Appendix 5.5). Moreover, “a letter of access for Research” was obtained because the patient interviews were conducted in NHS premises (Appendix 5.6). Process was followed by ensuring coverage of: obtaining informed consent from study participants; ensuring privacy of procedure; maintaining confidentiality and secure storage of data; and aggregation of results. The main difference was the number of Health Board approvals required in Scotland compared to Oman where research related requirements are standardized at a national level under the Ministry of Health.

5.3.6 Procedures for Consent

In Oman, primary health care facilities in urban (city) and rural areas were contacted by the primary researcher by telephone for the purpose of obtaining approval to interview a group of scheduled dental patients with specified criteria to ensure a range of responses (age 18-60, both genders, use or non-use of tobacco and alcohol, geographical region). A total of five primary care centres gave approval to having their patients interviewed and were provided with a copy of the study ethical approval as needed. Each of the dental patients was first approached by the assigned dentist and verbal consent was obtained. Patients were then approached by the researcher individually for formal written consent (Appendix 5.7) after receiving an information sheet (Appendix 5.8) which gave clear explanation about the study and its purpose. Patients were also informed that participation was completely voluntary and there was no harm or disadvantage in refusing to participate and they were free to discontinue at any point of interview process. The written consent was in both Arabic and English language to ensure clarity and transparency for Oman participants.

In Scotland, patient selection criteria were provided to dental clinic, and they were requested to screen the list of patients who had an appointment on a selected date. Upon patient approval to participate, the staff member introduced the patient to the researcher in the waiting area.

5.3.7 Privacy and Confidentiality

Each dental patient in Oman and Scotland was interviewed in a private room or quiet corner of a waiting room. Where possible, the room door was closed with an ‘interview in progress’ sign placed on the door. The interview was recorded and saved to computer file for transcription and analysis. The participating dental patients were informed that their recorded responses would not be shared or used except for research purposes. This issue was particularly sensitive in Oman, for example, where for cultural reasons, experiences with smoking and alcohol are not socially acceptable to disclose (though smoking and drinking exist in private). Confidentiality was assured by using unique ID numbers for Omani patients (OP1,OP2…, OP24) and for patients in Scotland (SP1,SP2…., SP24). After completion of each recorded interview, the selected dental patients were reassured

that the data obtained would be securely stored in accordance with University data security protocols, with access limited to the research team alone.

5.4 Results

A total of 48 dental patients were interviewed from the Sultanate of Oman and Scotland (n= 24 in each setting). The interviews were conducted in 2017 between February and March. Interviews were responsive to patient need and willingness to answer questions to various degrees and depths and therefore ranged in duration from 12 to 24 minutes each.

5.4.1 Characteristics of Participants from the Sultanate of Oman and Scotland

There were 24 patient participants from Oman (11 female [46%] and 13 male). There was some diversity in backgrounds: 20 Omani, two Egyptians, one Pilipino and one Moroccan. The eldest participant was 50 years old while the youngest was 22 years of age. The majority of the participants in Oman were non-drinkers and non smokers; only one Philipino was a drinker - there was one ex-smoker and one current smoker. Professionally, those participants were from various backgrounds: administrator, chief executive officer, students, policeman, private business owner, practicing nurse, and they represented both rural and city inhabitants (Table 5.1).

In Scotland, there were again 24 patient participants (15 female [63%] and 9 male). A third reported ‘non-Scottish’ country of origin. The age range was between 56 years to 24 years old. Among these, five were current smokers, eight were ex-smokers, and 11 were non-smokers. Out of the 24, 14 were alcohol drinker and 10 were non-drinker. The participants came from different back grounds, 12 were not working, six had manual and six non-manual occupations (Table 5.2).

Table 5.1 Demographic data for participants from the Sultanate of Oman

ID	Gender	Year of Birth	Geographical Area	Nationality	Occupation	Tobacco use	Alcohol use
OP1	M	1976	Swaiq - Urban	Omani	Admin Security	non-smoker	non-drinker
OP2	F	1976	Swaiq – Urban	Omani	Truck Driver	non-smoker	non-drinker
OP3	M	1996	Rustaq - Urban	Omani	Police man	non-smoker	non-drinker
OP4	M	1967	Swaiq – Urban	Omani	Watch man (School)	ex-smoker	non-drinker
OP5	M	1976	Rustaq - Urban	Omani	Royal Guard	non-smoker	non-drinker
OP6	F	1977	Muscat – City	Egypt	Chef	non-smoker	non-drinker
OP7	F	1975	Muscat – City	Egypt	House wife	non-smoker	non-drinker
OP8	F	1979	Muscat – City	Morocco	House wife	non-smoker	non-drinker
OP9	M	1968	Muscat - City	Omani	Employee at MOFA	non-smoker	non-drinker
OP10	F	1985	Alamerat - Urban	Omani	Police	non-smoker	non-drinker
OP11	F	1990	Awabi – Urban	Omani	Receptionist in Police hospital	non-smoker	non-drinker
OP12	M	1982	Swaiq – Urban	Omani	Staff -Nurse	non-smoker	non-drinker
OP13	F	1983	Fanja – Urban	Omani	Own Business	non-smoker	non-drinker
OP14	M	1969	Muscat – City	Omani	Health safety manager	current smoker	non-drinker
OP15	F	1964	Muscat – City	Omani	Business	non-smoker	non-drinker
OP16	M	1969	Muscat – City	Omani	Retired x-ray technician	non-smoker	non-drinker
OP17	F	1972	Barka – Urban	Omani	Not working	non-smoker	non-drinker
OP18	F	1990	Swaiq – Urban	Omani	Desk operator	non-smoker	non-drinker
OP19	M	1974	Muscat – City	Omani	CEO – chief executive officer	non-smoker	non-drinker

ID	Gender	Year of Birth	Geographical Area	Nationality	Occupation	Tobacco use	Alcohol use
OP20	F	1979	Muscat – City	Omani	Post graduate student	non-smoker	non-drinker
OP21	F	1974	Muscat – City	Pilipino	Domestic helper	non-smoker	drinker
OP 22	F	1981	Muscat – City	Omani	Student	non-smoker	non-drinker
OP 23	F	1990	AlMusanah – City	Omani	Student	non-smoker	non-drinker
OP24	F	1973	Muscat – City	Omani	Director of statistic and geographic information	non-smoker	non-drinker

Table 5.2 Demographic data for participants from Scotland

ID	Gender	Age	Country of Origin	Ethnicity	Occupation	Tobacco use	Alcohol use
SP1	M	27	Scotland	White Scottish	Manual	current smoker	drinker
SP2	F	36	Syria	Asian Arab	Not Working	non-smoker	non-drinker
SP3	M	41	Syria	Asian Arab	Not Working	non-smoker	non-drinker
SP4	M	37	India	Asian Indian	Non Manual	ex-smoker	non-drinker
SP5	M	57	Scotland	White Scottish	Manual	ex-smoker	drinker
SP6	F	56	Czechia	White Czech	Manual	current smoker	non-drinker
SP7	F	72	Scotland	White Scottish	Not Working	ex-smoker	non-drinker
SP8	F	27	Scotland	White Scottish	Manual	non-smoker	drinker
SP9	M	46	Scotland	White Scottish	Manual	ex-smoker	drinker
SP10	F	40	Italia	Black Italian	Not Working	ex-smoker	drinker
SP11	F	28	Scotland	White Scottish	Not Working	current smoker	drinker
SP12	M	54	Scotland	White Scottish	Manual	ex-smoker	drinker
SP13	F	67	Scotland	White Scottish	Not Working	current smoker	non-drinker
SP14	M	67	Scotland	White Scottish	Not Working	ex-smoker	drinker
SP15	F	65	Ireland	White Irish	Not Working	non-smoker	drinker
SP16	M	69	Scotland	White Scottish	Not Working	non-smoker	non-drinker
SP17	F	44	Scotland	White Scottish	Not Working	non-smoker	drinker
SP18	F	44	Deutschland	White Dutch	Non Manual	non-smoker	drinker
SP19	M	34	Scotland	White Scottish	Non Manual	non-smoker	drinker
SP20	F	32	England	African British	Non Manual	non-smoker	non-drinker
SP21	F	72	Scotland	White Scottish	Not Working	non-smoker	non-drinker
SP 22	F	32	Scotland	White Scottish	Non Manual	non-smoker	non-drinker
SP 23	F	49	Scotland	White British	Non Manual	ex-smoker	drinker
SP24	F	65	Scotland	White Scottish	Not Working	current smoker	drinker

5.4.2 Frequency of Dental Clinic Visits and Reasons for Attending

Participants were asked about the frequency of their dental clinic visits in the last five years and the reasons for their visits. In Oman, the majority had visited the clinic between 2-4 times over five years. Those visits were reported to be mainly for general check-ups and / or follow up, as well as scaling and polishing (oral hygiene). One dental patient reported that the purpose for their dental clinical visit was for an implant. In contrast, the majority of the participants from Scotland visited the dental practice twice a year for each of the last five years. Similar reasons were reported for their visits, mainly being check-up / routine dental appointments.

In general, this reporting of attendance for routine check-ups is a facilitator to opportunistic COE, that is patients presenting for pain / treatment needs only would negate some opportunity for routine checks or checks targeted based on risk factors.

5.4.3 Knowledge of Oral Cancer Causes

On a scale from “no knowledge” to “very good knowledge”, 9/24 (37.7%) of dental patients (one Egyptian, one Philipino, and seven Omanis) reported “no knowledge” about the causes of mouth cancer, while 11/24 (45.8%) of patients (one Egyptian, 10 Omanis) reported “slight/little knowledge” about mouth cancer causes. Three patients (12.5%; one Moroccan and two Omani) had “some knowledge” and just one Omani patient reported “good knowledge” (nobody reported “very good knowledge”). In contrast to the Oman participants, Scottish patients reported slightly better knowledge in relation to the causes of mouth cancer, and related that this came mainly from media sources. Two patients 2/24 (8%) said they had good knowledge, 20/24 (83%) reported having “slight/little knowledge” and only two female patients 2/24 (8%) reported having “no knowledge”. As reported, dental visits were more frequent in Scotland which may be seen to be in accordance with this higher self-reported knowledge.

5.4.4 Experience of COE

Patients were asked if anyone from the dental team checked them for mouth cancer inside the mouth (by retracting the cheeks, pulling the lower lip, grasping the tip of the tongue and looking at the posterior lateral aspect of your tongue). In Oman, the dental patients

reported little recall of experiencing a conventional oral examination of the tongue / mouth when they received dental care:

"No, pulling the tongue they are not doing". (OP12)

"No, they are not doing like this, they're seeing for the, I don't know what they call...?" (OP12)

"Never, all my life they didn't do like this" (OP 15)

"Frankly, no. They were just focusing on my teeth only" (OP 18)

There was a broadly similar picture in Scotland. Intra-oral checks for mouth cancer were reportedly rare. Just two patients said they had received this type of check-up by their dentist:

"[…] He always asks me to stick my tongue out to the left and to the right. Is that associated with it? Yeah" (SP4).
"I've heard about it. The first time I'd ever heard about it was in this dentist. I'd heard about mouth cancer before but the first time I'd ever heard of a dentist giving my mouth a check-up was when she lifted up my tongue and she had looked inside my mouth [...] " (SP5).

Findings were similar when patients responded to questions about experiencing or being aware of receiving extra-oral examination:

- Participants from Oman:

"He did not check outside my mouth" (OP 1).

"no these things did not happen, she checked my teeth, did the x-rays, she told your tooth is broken, and scratches, you need some sets to clean and treat it. but using that gauze and checking up and down, not happened".(OP 5)

"No, just a general look." (OP 13).

- Participants from Scotland:

"No, I don't think I've had that, no." (SP1)

"I've not noticed. They might have done it, but I've just not been aware of it. Or I might have just thought they were trying to position my head, so…"(SP3)

Just one patient in Scotland felt they had been checked extra-orally, saying:

"Aye, I remember her doing all sorts of different things because I was enquiring" (SP5).

This is in contrast with findings from the previous chapter, whereby this type of check was reportedly common. Of course, patients not being aware of experiencing this type of check is not in itself a barrier. But it does suggest that raising awareness might prove fruitful, in that patient expectation might be a potential driver to professional duty / responsibility.

5.4.5 Patient Knowledge

Having relayed their experiences, patients were asked whether they were aware that they could be checked for mouth cancer by dental teams.

Tables 5.3 and 5.4 show responses from each country for this item, coded by COM-B / TDF and then collated in terms of whether they enable (facilitators) or inhibit (barriers) opportunistic checks by dental teams.

Table 5.3 Barriers/ facilitators presented by patient knowledge of mouth cancer checks in Scotland (B= barrier; F= facilitator; E= equivocal response)

COM-B/ TDF CODING

Patient knowledge/awareness

Social opportunity/influence for practitioners (also may affect motivation)

Some resource (physical opportunity) implication as time would be required to increase knowledge/ raise awareness

CODING SUMMARY

Lack of patient knowledge indicates a potential barrier for dental professionals, as patients will not expect, or request mouth cancer checks and may need more explanation/ information before checks are carried out

Question: Do you know you could be checked for mouth cancer by dental team?

ID	Responses	B	F	E
SP1	No I didn't know that.	x		
SP2	Yeah, I think happy, yeah. When I know about cancer, mouth cancer risk, yeah, in the future, maybe, yeah.		x	
SP3	No, just a general check, not for cancer.	x		
SP4	No.	x		
SP5	[Patient not asked the question]			x
SP6	Yes, she describes everything.		x	
SP7	No, do you need to ask for that?	x		
SP8	[Patient not asked the question]			x
SP9	[Patient not asked the question]			x
SP10	[Patient not asked the question]			x
SP11	I know that, aye, I think so, aye.		x	
SP12	I never knew that, no. I never knew that, honestly.	x		

SP13	No, I didn't know that but, as I say, when you're getting your check-up, she does give you a good check-up, but I didn't know that they could do all that...	x		
SP14	No, I didn't know that.	x		
SP15	No.	x		
SP16	No.	x		
SP17	[Patient not asked the question]			x
SP18	Well I haven't really been thinking about it, but then my mother-in-law was sent for a biopsy [inaudible 15:08], yes of course, it makes sense. Of course they check. But then I hadn't realised that by sticking my tongue out that's how they do it.			x
SP19	No.	x		
SP20	Well, I assumed they would probably know, they would notice it because they're dentists, yes.		x	
SP21	Oh, no, no, no, I do believe they do, yeah.			x
SP22	[Patient not asked the question]			x
SP23	Yeah, because they ask…when they check you, they ask you to move your tongue around and to check all the different parts of your mouth, and I assume they're checking for abnormalities, and things like that.		x	
SP24	I didn't, no.	x		
SCOTLAND SUMMARY		11 (46%)	5 (21%)	8 (33%)

Table 5.4 Barriers/ facilitators presented by patient knowledge of mouth cancer checks in Oman (B= barrier; F= facilitator; E= equivocal response)

COM-B/ TDF CODING

Patient knowledge/awareness

Social opportunity/influence for practitioners (also may affect motivation)

Some resource (physical opportunity) implication as time would be required to increase knowledge/ raise awareness

CODING SUMMARY

Lack of patient knowledge indicates a potential barrier for dental professionals, as patients will not expect, or request mouth cancer checks and may need more explanation/ information before checks are carried out

Question: Do you know you could be checked for mouth cancer by dental team?

ID	Responses	B	F	E
OP1	Honestly I don't know, if I knew I would ask him if he could check me for mouth cancer. But thanks to Allah that they did clean my teeth and I feel better now.	x		

OP2	No I don’t know. I only know the dentist for teeth only not for cancer screening.	x		
OP3	No I don’t know about that, because when we went to him just we thought about teeth pain and we don't have background about what he does.	x		
OP4	Of course the doctor know more than the patient, he know everything.			x
OP5	Nobody did it unfortunately, …. no they are not doing it	x		
OP6	No I dont know, I can't evaluate..	x		
OP7	I don’t know actually, this is my first time hearing this. […] But I don’t know about their ability in doing this screening; It’s my first time I hear that they can do that.	x		
OP8	It depends on the dentist, if he has the experience.			x
OP9	This is my first time I am hearing this from you.	x		
OP10	I don’t know that, this is my first time I am aware about this screening.	x		
OP11	I know he can do it, but at the same time I cannot blame him, because of the number of patients waiting outside. But if it is part of his role then he should fulfil this role completely, and he should not be wary about being behind the schedule or late. And we need to be patient.		x	
OP12	I don't know.	x		
OP13	No, I don’t know. I think just if I ask them.	x		
OP14	[Participant not asked the question]			x
OP15	They can but if they have this information they should do it for the patient.			x
OP16	No, no I didn't know, I didn't know.	x		
OP17	I know this […] they put the stick inside and he can open your mouth then put a light, the laser and they check only like this […]		x	
OP18	No, nothing happened. No, this is my first time.	x		
OP19	No, I didn’t know that. Nobody informed me about it.	x		
OP20	No.	x		
OP21	Yes, I know because the other dentists they know how to check but they didn't do for me.		x	
OP22	No, I don’t know. But I think if they could do that it would be better.	x		
OP23	No.	x		
OP24	No. I don’t know.	x		
OMAN SUMMARY		17 (71%)	3 (12%)	4 (17%)

Tables 5.3 and 5.4 show that on balance patient (lack of) knowledge can present a barrier to uptake of checks, especially in Oman. This may be important in that the evidence and

guidance reviewed in this thesis shows considerable recognition by global associations that the scope of practice in primary care has certainly expanded from simple treatment of oral disorders to include a demonstrable commitment to standards of disease prevention, health promotion, and health maintenance. Patients being unaware of this is a potential barrier to address.

5.4.6 Patient views on acceptability

Having relayed their experiences and knowledge, patients were asked whether they were happy to be examined in this way. Tables 5.5 and 5.6 show responses from both countries for this item, again coded by COM-B / TDF and then collated in terms of whether they enable (facilitators) or inhibit (barriers) opportunistic checks by dental teams.

Table 5.5 Barriers/ facilitators presented by patient happiness to accept mouth cancer checks in Scotland (B= barrier; F= facilitator; E= equivocal response)

COM-B/ TDF CODING Patient happiness/ acceptability (could be down to a number of things including previous experience but is motivational) Social opportunity / influence for practitioners (also may affect motivation and capability – skills in dealing with patients who are less accepting) Some resource (physical opportunity) implication as time would be required to address reasons for patients' lack of willingness **CODING SUMMARY** Patients happiness to accept indicates a potential barrier for dental professionals, as patients may refuse, or could require more time, effort and skill before checks are carried out				
Question: Would you be happy to be examined during your appointment? If no, why not?				
ID	**Responses**	**B**	**F**	**E**
SP1	No I wouldn't mind aye.		x	
SP2	Yeah, yeah, yeah.		x	
SP3	Yes, no problem, okay.		x	
SP4	Yeah, that's fine.		x	
SP5	Yes. Aye. Yeah.		x	
SP6	Aye, because the earlier it's diagnosed there is a higher chance to recover from it.		x	

SP7	I would feel okay about it, because they're only…you know what I mean, they're not giving you jags and all that. No, I would be quite happy.		x	
SP8	Yeah, because if you were coming for a check-up and it was a part of it, yeah, I wouldn't mind.		x	
SP9	Aye, any visit, I don't mind, aye.		x	
SP10	Yes, it's okay, it's for my own good, it's for my own health.		x	
SP11	I would feel okay, aye, happy.		x	
SP12	Oh no, I wouldn't bother. They may have done it, I've been unaware. But I don't think they've done it, but they may have done it.		x	
SP13	No problem, because, as I say, I've not got hardly any teeth left. I don't mind that because, as I say, the earlier you can have something like that, the better.		x	
SP14	Aye, of course I would, aye.		x	
SP15	Yes, but I'd rather say myself than you say it to them.			x
SP16	Yeah, of course, hmm; As long as he doesn't hurt me! I'm a wimp when it comes to pain.			x
SP17	No, I felt reassured because it was the first time it had ever happened. I didn't feel as if I had it, I felt as if I was with a dentist who was really good at her job, so that was good.		x	
SP18	Yeah, totally. I don't know whether it would make much…		x	
SP19	Yeah, I think that's important, because you can't skirt around these issues, you know. Ignorance is bliss, but it's not bliss when it's too late. So it's important. Very important. Very happy.		x	
SP20	I'd be happy.		x	
SP21	I wouldn't object to that, no.		x	
SP22	To be honest I would trust them to know what they were doing. They're the professionals.		x	
SP23	I wouldn't mind.		x	
SP24	Hmm. I'd be very interested, yeah.		x	
SCOTLAND SUMMARY		0 (0%)	22 (92%)	2 (8%)

Table 5.6 Barriers/ facilitators presented by patient happiness to accept mouth cancer checks in Oman (B= barrier; F= facilitator; E= equivocal response)

COM-B/ TDF CODING

Patient happiness/ acceptability (could be down to a number of things including previous experience but is motivational)

Social opportunity / influence for practitioners (also may affect motivation and capability – skills in dealing with patients who are less accepting)

Some resource (physical opportunity) implication as time would be required to address reasons for patients' lack of willingness

SUMMARY

Patients happiness to accept indicates a potential barrier for dental professionals, as patients may refuse, or could require more time, effort and skill before checks are carried out

Question: Would you be happy to be examined during your appointment? If no, why not?

ID	Responses	B	F	E
OP1	Yes nobody know so better for protection.		x	
OP2	It will be good, it will motivate me to take more care.		x	
OP3	No I don't have any objection, if the checkup makes me in healthy situation.		x	
OP4	I don't mind, this is for my benefit and I learn from him.		x	
OP5	Not at all, he is welcome to do the test		x	
OP6	If he did this would indicate that the doctor really understands his/her job perfectly and capable and this will gain him/her a good reputation when I praise him/her in front of my friends and people.		x	
OP7	As long as this is a new thing it's good thing.		x	
OP8	You know, prevention is better than cure, and I don't mind to be checked.		x	
OP9	Of course, I don't mind Because it's for my health benefit. As you know prevention is better than cure. If the dentist explained to me what he want to do and why he want to do it for example, I will be happy to help them in participating in reducing the incidence of this disease.		x	
OP10	For sure I will be comfortable for my health benefit.		x	
OP11	I don't mind, because of my health		x	
OP12	If they are expert in this no problem for me, he is a doctor he can do for me what to be done.		x	
OP13	For me, better if you check without telling. If he found something wrong, better if he tell me, but if first check nothing wrong, only check, I wish if they didn't tell me because of this reason.			x
OP14	Yes, of course I would be happy.		x	

OP15	Yes. I'll be more happy if I don't have cancer. I mean, they will tell me if I have or not I have or don't I have, I mean. They tell me immediately that means I'll be happy, yes, if I have or not.		x	
OP16	Yes, I would be happy. If I know this is because of the to know if I have something like cancer or anything bad, it is good for everyone to do it.		x	
OP17	Yes, I'm very happy to receive this and to learn something and for the future and for maybe our friend, our family. […]		x	
OP18	I would love to be. I think we should have this kind of check-up once a year at least. Well, I think I have to make sure that everything is okay with me, so I would love to be checked.		x	
OP19	Sure. Just to have the comfort that I don't have any such problems with my mouth and teeth.		x	
OP20	Yes, of course. Because it's a sort of protection now if you are telling me that if the doctor checks my mouth cavity for the cancer's appearance; so I assume it could be an early detection of any problem, so I would be happy really.		x	
OP21	Yeah. Because I know if I have cancer or not. Yeah, to prevent.		x	
OP22	Yes, of course. Because first of all this will save my life. If for example there is a certain level for having this kind of cancer, so I think, yeah, I would be happy and I would appreciate their concern about it.		x	
OP23	Yes, yes. Yes, because to be in the safe side, as you say in Arabic [speaks Arabic]. In English, is that prevention better than cure.		x	
OP24	Yes, of course. To make sure about my health, and to check if I have anything, it will be...it will give me some information.		x	
OMAN SUMMARY		0 (0%)	23 (96%)	1 (4%)

Table 5.5 and 5.6 show an encouraging picture in terms of patient happiness / motivation to be checked. There were only one or two slightly equivocal responses with regards to being told results or feeling pain. This willingness is an enabler for dental professionals carrying out checks and should be fed back to the profession as part of intervention / recommendation (see Chapter 6).

The next question of interest was to gather patient preferences with regards to OHCPs explicitly speaking of the checks in terms of oral cancer. Professionals in the previous chapter reported some worries about introducing and using cancer terminology with patients in relation to opportunistic screening - assuming this may not be acceptable to patients. Interestingly, this broadly appeared more of a motivational barrier in Omani patients. Scottish patients were split on whether they would broadly welcome such discussion. Patients were asked to rate their feelings in response to the question "how do

you feel about the dental team using the term cancer?" using a 5-point Likert scale from not happy at all to very happy. More than half of the patients from Scotland reported being "happy" or "very happy"; no patients from Oman were "very happy" and some were "not happy at all". This is an emotional barrier in Oman, with the psychological impact of the term cancer coming through in open-ended responses which are tabulated in Tables 5.7 and 5.8.

Table 5.7 Patient views from Scotland on professionals using the term mouth cancer (B= barrier; F= facilitator; E= equivocal response)

COM-B/ TDF CODING Patient motivation Social opportunity / influence for practitioners (also may affect motivation) Some resource (physical opportunity) implication as time would be required to facilitate communication using different terms if necessary **CODING SUMMARY** Lack of patient preference for using the term indicates a potential barrier for dental professionals, as patients will be resistant to checks if associated with the fear of the term and may need more careful communication or explanation of what is happening before/ during checks.				
Question: How would you feel about dental team using the term "mouth cancer check" while examining you? Why, why not?				
ID	**Responses**	**B**	**F**	**E**
SP1	Well, very happy, to me, means, you know, it would happen absolutely every time.		x	
SP2	It would. It would a wee bit. I'd probably go, oh my God, I hope they don't see anything. It would terrify me a wee bit, but I wouldn't say, oh no, don't check. Yes, I'd be fine.		x	
SP3	Because you can't skirt around these issues, you know. Ignorance is bliss, but it's not bliss when it's too late. So it's important. Very important.		x	
SP4	I don't think I've got any, so it wouldn't terrify me, 'cause I wouldn't expect them to find anything.		x	
SP5	Very happy		x	
SP6	No, no. If you've got cancer, you've got cancer, so better to know about it than not. So I'd be fine.		x	
SP7	[Not asked the question]			x
SP8	Well, I think, as you say, the earlier…if they find out earlier, there's a chance of sorting it out. That's why, yeah.		x	
SP9	No, no, cancer doesn't frighten me anymore, because		x	

	I've already had it. It used to be a big scary thing, but some cancers can get cured. […] I had the bowel cancer, and when I found out there was a bowel cancer they discovered the lung cancer, and they thought it was different. So that's how I got the lobe took away. But when the pathology came back, they were the same, so I was lucky […]			
SP10	No, no. It's just a check-up, so I wouldn't mind.		x	
SP11	Just in case there's something there and I've not noticed it, maybe they can, so...aye.		x	
SP12	It would scare me, no, no, no, I don't like going for the scan or those things, no, no, no.	x		
SP13	No, it would maybe scare me if I haven't spoken to you but because I know that it's a good idea, yeah.		x	
SP14	It wouldn't bother me because they're trying to look out for you and check any early signs.		x	
SP15	I would feel okay about it, because they're only…you know what I mean, they're not giving you jags and all that. No, I would be quite happy.		x	
SP16	Very happy		x	
SP17	Aye, probably a good idea actually. Obviously to detect it at an early stage. They would know better. 'Cause you wouldn't know you had it, you know, myself obviously, if I had something like that.		x	
SP18	Happy		x	
SP19	Happy		x	
SP20	[Not asked the question]			x
SP21	I don't know. I suppose it just, sort of, puts the idea in your head that there might be…you know, you go to the dentist thinking, oh, I hope I don't have to have dental treatment; but then it might make you think of another problem that you haven't thought about.	x		
SP22	No. No, it wouldn't terrify me. I'd feel more content if they did do it, yeah.		x	
SP23	Happy		x	
SP24	I don't know. I guess just that… I think I would be very happy if it was already something that was on my radar. I think it's just that it's something else that I've not been thinking of that perhaps I ought to, and if they started checking for it and telling me, that would be absolutely fine […]		x	
SCOTLAND SUMMARY		2 (8%)	20 (88%)	2 (8%)

Table 5.8 Patient views from Oman on professionals using the term mouth cancer (B= barrier; F= facilitator; E= equivocal response)

COM-B/ TDF CODING

Patient motivation

Social opportunity / influence for practitioners (also may affect motivation)

Some resource (physical opportunity) implication as time would be required to facilitate communication using different terms if necessary

CODING SUMMARY

Lack of patient preference for using the term indicates a potential barrier for dental professionals, as patients will be resistant to checks if associated with the fear of the term and may need more careful communication or explanation of what is happening before/ during checks

Question: How would you feel about dental team using the term "mouth cancer check" while examining you? Why, why not?

ID	Responses	B	F	E
OP1	Yes I encourage to tell the patients, who knows I might don't know about it, and the disease is progressing increasing. So better to inform.		x	
OP2	I see it difficult, I prefer he do the treatment and the check-up without using the word cancer. If he use it I might not come back. I will be in doubt about.	x		
OP3	In the fact the cancer word is create panic inside me and our society and it is means for us dangerous disease so when the dentist ask us to do this checkup and we may feel surprised, because I'm scared it might be in me.	x		
OP4	He should tell, that I am doing this and this, to have benefit from doctor.		x	
OP5	The word cancer first is a strong word and people interact with it and get scared and will guess that doctor might saw something, will have periodical check , will see the way, the gum, the tongue, without using the word! […] Even there is nothing , frightening will be there	x		
OP6	I would prefer if he/she does not mention it, Cause it makes me over think when I heard "cancer".	x		
OP7	I would like him to tell me, it is also ok with me, so I can learn from him. At the same time you know we have a lot of new diseases which developed recently that we never hear about it. So when he tell me it is for my own education.		x	
OP8	[…] I prefer he don't tell me first. This is the human nature- [to] have some phobia.	x		
OP9	I prefer he use the word "cancer". Because we are in the era that a person should know everything about himself. So, he can take care and follow all the		x	

	preventive steps with the dentist, this is my point of view. There is nothing to be hidden.			
OP10	I prefer he do the check up without telling me what he is doing. When he discover something not normal then he should explain to me because you know, when we hear about these type of disease we get scared and feel to faint.	x		
OP11	It is better if he tell me. It is right that the word cancer is big, but it will create awareness specially for young generation. You come for something but you will discover more things.		x	
OP12	Because I am health care worker no problem for me. It is normal word because we are screening for [inaudible] females for HIV like this for my safety, for my health.		x	
OP13	Because this disease is not easier, and this word is not easier to my ear, I don't want to know. Because if I know, if it's there or not, directly I'm thinking why, why, why. Even if I haven't. But, you know, this is dangerous. So we didn't accept it ourselves. Not happy.	x		
OP14	I prefer, because I prefer to tell that.		x	
OP15	Well, yes, why not? They said sometime…they should…I think so depending on the patient. Some patient they don't like they hear about their cancer.		x	
OP16	Not nice, not nice. Because I think if they can use another word like we will check if there is any cysts or anything […] because many of the patients they don't have idea of this, they thought maybe he saw something so because of that he said. So they will start to think and psychiatrically they will think I have this thing.	x		
OP17	[…] word cancer it should be. Yes, yes.		x	
OP18	You can say happy. Well, at least I'm going to feel like they're taking enough care of me.		x	
OP19	Maybe I would be like worried at the beginning, but afterwards… I mean to do it, it would be fine. I mean it will just comfort me, because in case if I have it I might have to…I might need to be treated. […] So I don't mind. It might be scary but it's better to know than…earlier than to know later, you know.		x	
OP20	Yeah, I think it…it is quite heavy to digest when someone says it's a cancer check up, or just cancer check up. Yeah. But I believe it has to be maybe in a different way where maybe the patient shouldn't know much about it and it comes as a routine check up while doing a routine filling or whatsoever, rather than saying a cancer; because I don't know other countries how they feel it, but maybe as Middle East, we are in Middle East, they feel it quite heavy to just tell them that it's a cancer check up or something like that […]	x		
OP21	Not sure. Because I'm not sure because it's just tricky			x

	and then I'm not sure also if I have cancer.			
OP22	[…] I think I would say happy, I would be happy, yeah. Although it would scare me I would be happy because I know that the doctor's doing his job and taking care of his or her patients. So this would also make me feel comfortable that they are taking care of me and that's why.		x	
OP23	Not sure. Maybe first I will scare about the word cancer, but I want to check because this is better for me.			x
OP24	I'm not sure really, but I think the word cancer is a difficult word to accept, so it's...I feel I will not be happy. Because cancer is fearing, you know, when you...it's...I don't know how to say, but it's...it's not easy word to accept or to feel you are fine, it makes you worry about your health, so that why, or maybe we prefer not to hear this word.	x		
OMAN SUMMARY		10 (42%)	12 (50%)	2 (8%)

Tables 5.7 and 5.8 show that most patients in Scotland are willing to be informed by the dentist that oral screening for cancer is taking place. This is an enabler that can motivate the dentist to carry out checks and speak openly to the patient about it. In contrast, over two fifths of Oman responses indicate a preference not to be informed about cancer screening directly based broadly on fear of the disease and negative connotations of the term.

So, while patients in Oman and Scotland were happy to be examined systematically, there are mixed responses in terms of having explicit cancer discussions. Especially in Oman there is a general preference that OHCPs do the examination but not use the word "cancer" in front of the patient. This is a potential barrier – as professionals have a duty to a) explain what they are doing and b) ask patients if it is acceptable. This is an implementation barrier in the social influence / opportunity sphere that can potentially be addressed (see Chapter 6).

Finally, patients were asked about the acceptability of professionals using a risk prediction tool for targeting those at high risk of oral cancer for preventive care and interventions. A number of such tools have been developed to be used in the clinical settings for predicting cancer risks in individuals (Kim et al., 2004; Weber et al., 2017). Patients were presented

with the example of a prototype tool developed by the INHANCE network (INHANCE, 2018).

Overall, dental patients participating in this study responded positively to areas probed by the researcher using the INHANCE tool as an example. Having said that, dental patients from Oman once more had cultural concerns (social influences) for some types of questions (in reference to smoking and drinking). Scottish patients generally saw such tools as acceptable, with one patient being concerned about the insurance implications of disclosing health behaviours (these are motivational barriers or facilitators).

Both patient groups felt they might on balance prefer to go through a risk prediction tool with the dentist (i.e. through direct communication) rather than fill it in themselves e.g. electronically in the waiting room. They felt this would essentially serve their overall treatment plan better in the long run, avoid unexpected technical issues using applications, and ensure they could obtain clarification directly from the dentist for unclear questions if the need would arise. Whilst understandable, this is a potential barrier in terms of the time / resources available to the dental team, who would generally prefer some way of expediting less demand on the consultation time itself, although accuracy could be an issue of self-completed by patients.

Patients were asked how they would prefer the risk level to be presented, with some indications for a 'traffic light' system (red, amber, green):

"It's more clear. It explains exactly where I am. Percentage might tell you exactly where are you, but here might be some mistake. But if I belong to low category there must be a range that I belong to that" (OP7)

"The traffic light: I'm quite attracted to the traffic light system. When I was working, I introduced a scheme to monitor repairs, and it was a traffic light system we used, so traffic light system is quite a good idea" (SP6)

Others preferred a basic number / percentages as more acceptable due to ease of interpretation, clearer measurement, and the ability to see changes over time (e.g. a worsening):

"..So if we talk about colours - how much in red? How much in yellow, how much in green. So, percentage is more clear" (OP5).

"Maybe because the percentage is different than other category. May be with category I feel I am at risk, but with percentage I can measure myself were I am out of one hundred and I will take better care of myself" (OP3)

"Traffic lights or a high/low risk factor is quite ambiguous. Doesn't really tell us too much but a risk factor…a percentage, you could really…you know, if it was under a certain

percentage, you would say, well…it gives you something to work to, to the next time you were to score it. Whereas a traffic light system might not reflect that. Whereas a percentage, you could go up from 25 per cent to 33 per cent the next visit and you're like, I'll need to make further changes. It, kind of, creates a pattern. It tells us, you know, take it down" (SP3)

"It would just be easier to gauge" (SP13).

Coded answers on whether patients were happy to be risk graded based on their social history are shown in Tables 5.9 and 5.10.

Table 5.9 Perceptions on having a risk score from Scottish patients (B= barrier; F= facilitator; E= equivocal response)

COM-B/ TDF CODING Patient preference/motivation Social opportunity / influence for practitioners **CODING SUMMARY** *Lack of patient acceptance indicates a potential barrier for dental professionals, as patients may be more collaborative re. their care if they know their risk level*				
Question: How would you feel about dentist telling you a risk score as high, medium, or low for mouth cancer based on your personal information – e.g. smoking, alcohol, age, years of education, family history?				
ID	**Responses**	**B**	**F**	**E**
SP1	Oh I'd be fine if they were doing that.		x	
SP2	Hmm…high, medium and low. High, medium is good. High, medium.		x	
SP3	Yes, no problem.		x	
SP4	Yes, I think it would be helpful.		x	
SP5	Aye, it's alright receiving it, but it's…you might not have it. You could be a smoker or a drinker and never get mouth cancer. And the other way about. You could have smoked and drink all your life and still not get it. So…I'd be okay to receive it, aye. Yeah.		x	
SP6	She doesn't want to know so she's not happy about it.	x		
SP7	If I needed it? If I was at risk, yes, I would take…Happy.		x	
SP8	Yeah, I probably would be happy if they did some sort of risk score to make you maybe a wee bit more aware of your chances of getting it.		x	
SP9	I'd be happy.		x	
SP10	Oh no- if I'm not included it's okay, but if they say I may,	x		

	then I don't want any bad news. Not happy somehow.			
SP11	Aye, okay, no bother.		x	
SP12	Aye, I'm happy with that as well.		x	
SP13	I think that would be a good thing. You know, if I go out one day a week, this is an extra day for me, so no, I would...I think it would be a good thing. I would be happy for them to do that.		x	
SP14	It wouldn't bother me, aye.		x	
SP15	Fine, yes.		x	
SP16	No problem, no. That would be fine.		x	
SP17	I don't think that would even effect my…I think it would be really positive. I think that the more people that are smoking…we live in the west of Scotland and it's a real drink culture and alcohol as you know…so I think it would be really positive, especially if you're saying it to children, you know, teenagers, you know, and it starts to maybe make them think when they come to the dentist about their teeth and stuff.		x	
SP18	Well, yeah, risk scores, I would want to know but I wouldn't want the insurance companies to know. What gets done with this information if you get the risk score and it gets written down […]?			x
SP19	Because I think it's important for people to find out, you know, and just be aware that mouth cancer is an issue. And also if there is a risk, then it would be advisable or if…even if there was maybe a visible sign of mouth cancer, then I think it's perfectly within the rights of the dentist to tell the patient to stop drinking or smoking or doing whatever.[…]		x	
SP20	I think I'd be happy, it would be fine. It won't bother me in any way, no.		x	
SP21	[…] Make you feel better, if you knew you were, you know, you were at low risk.		x	
SP22	I would be absolutely fine about receiving that. […] Yes, I think if you're going to give someone a score, particularly if you tell them that they're at high risk, you would want some kind of reassurance after that that you're at high risk, so from now on during your check-ups we will check for that as well if we've got your permission, that kind of thing. I think that would be really good. But on its own it might just be, oh dear, this is something else I have to worry about.		x	
SP23	Oh well aye. I wouldn't say that I would be happy but I wouldn't be like not happy. I wouldn't be over sure either because it is a good thing. I would say in between not sure and happy […] Oh I'd be fine if they were doing that.		x	
SP24	Yeah, I'd be quite happy, I suppose, receiving a risk score, yes.		x	
SCOTLAND SUMMARY		1 (4%)	20 (83%)	3 (13%)

Tables 5.9 and 5.10 show coded data indicating that the participants from both settings broadly welcomed the idea of having a risk score or a risk-level categorisation based on social history / modifiable risk factors. This could be an important driver for preventive care and a social facilitator towards conducting clinical oral examinations.

Patients were finally asked whether they would be happy to visit the dentist for a mouth cancer check more often than normal (3-6 months) if deemed to be at high risk.

Table 5.10 Perceptions on having a risk score from patients in Oman (B= barrier; F= facilitator; E= equivocal response)

COM-B/ TDF CODING Patient preference/motivation Social opportunity / influence for practitioners **CODING SUMMARY** Lack of patient acceptance indicates a potential barrier for dental professionals, as patients may be more collaborative re. their care if they know their risk level				
Question: How would you feel about dentist telling you a risk score as high, medium, or low for mouth cancer based on your personal information – e.g. smoking, alcohol, age, years of education, family history?				
ID	**Responses**	**B**	**F**	**E**
OP1	Well, it is okay, he is the doctor and specialised so…..okay.		x	
OP2	I don't mind to share my information, for my benefit.		x	
OP3	[It] means he will give me which category I belong… means if it's low or high or medium. I think its ok to me…. I'm happy... so happy		x	
OP4	Its good actually … Sure not. I don't mind … they are only questions.		x	
OP5	No problem for me		x	
OP6	Well, since there is something in the favour of the patient and all this in order to come up invent or discover a cure for a better health, I would be happy in providing the right answers.		x	
OP7	No problem.. it is a research to help people, I don't mind.		x	
OP8	No problem and I will not object, but again it depend on person		x	
OP9	Honestly, If he tell me that I belong to low risk group, I will be happy and I will take care and maintain my health		x	

	status. If someone at higher risk, I think he will try to prevent himself from that by trying to reduce smoking for example.			
OP10	Ya, no problem, I accept it		x	
OP11	I think its good thing, as it will help them and guide them to know what to do with the patient.		x	
OP12	They will be aware where they are from the cancer.		x	
OP13	Happy. Because I want to know the information and I feel they're honest with me. If this affect, I like it or not, but the truth is should I know it. Yes. And I want to know the ways how I protect myself and protect my kids. I have three kids, so I should know all information. I like it.		x	
OP14	It's good to inform me and to warn me. Warning in this kind of things is good.		x	
OP15	I'll be happy if I don't have…I will not get cancer. I'll be much happy.		x	
OP16	For me, I will be happy. Because now nobody care about the patient when they go to the hospital and mention with them these things. So if the doctor say after the check-up and everything and tell me after asking about tobacco and this and tell me if you have risk to have this and this it is good for me, because I will feel his care and his - not like I'm going only for remove the teeth, I'm going and go out. So I feel it is very good, yes.		x	
OP17	Very happy, very happy. […]		x	
OP18	I would be happy, it's okay. […]		x	
OP19	Yeah, sure. I don't mind….Yeah, I'd be very happy to know that I'm low risk….And if I get high I'd be upset. I mean I'd be sad if they tell me I'm high score….That means I am sick and I'm at risk, a high risk…..Yeah, it is good. It's a good… It gives me some indication, you know, somehow to know that what is my level or my chances of having cancer or having some sickness.		x	
OP20	Yeah, I'm very happy because, as I told you, that it's going to be good too for precaution.		x	
OP21	Because I'm sorry maybe I'll become happy. Because I know which is...if I have a medium or high or low group of cancer like that. Because it prevents...it prevents the cancer.		x	
OP22	Not sure.			x
OP23	I will be happy, because it is better to know before the distance, so what the...will be...do about me, and for what will check.		x	
OP24	I think yes, and because it's a type of knowledge which the patient should know and show, based on that thing he can feel what is the riskiness about his health, so I think it's good to know this information.		x	
OMAN SUMMARY		0 (0%)	23 (96%)	1 (4%)

Table 5.11 Views on visiting the dentist every 3 to 6 months if high risk- Scotland (B= barrier; F= facilitator; E= equivocal response)

COM-B/ TDF CODING Patient preference/motivation Physical opportunity / resource issue for practitioners **CODING SUMMARY** Lack of patient attendance is an opportunity barrier				
Question: Would be happy to visit the dentist for a mouth cancer check more often (3-6 months) if dentist told you were at higher risk?				
ID	**Responses**	**B**	**F**	**E**
SP1	Oh aye. Oh if I was at high risk I'd be back every day.		x	
SP2	Yeah, yeah.		x	
SP3	Yes, no problem.		x	
SP4	Yeah, I would do that, yeah.		x	
SP5	Oh probably more, yeah. Aye. Every three months probably. Aye. Just to keep on top of it.		x	
SP6	[Patient not asked the question]			x
SP7	Uh-huh.		x	
SP8	Yeah, I would do that if I was a high-risk, yes.		x	
SP9	Yeah.		x	
SP10	It would be difficult, I don't like visiting, it scares me a lot, yes, that is why I just this time with my teeth, it would be difficult I think.	x		
SP11	Aye, maybe, aye.		x	
SP12	Yeah.		x	
SP13	Well they probably would recommend it. If they recommended it, then I would just say that's fine...		x	
SP14	Yes, aye.		x	
SP15	Yes.		x	
SP16	I suppose it depends on if you're high risk, how long it takes to identify. I mean, if I was at high risk of cancer…Yeah, come more often, yeah. Yeah, yes, I would think so, yes. More often than the normal six months […]		x	
SP17	Aye, you would definitely be coming back more often, aye.		x	
SP18	If I was told I was at high risk, then yes.		x	
SP19	Oh yeah. Increase…definitely increase the [appointments] to whatever's…you know, affordable…		x	

SP20	Yes, of course. I would, yes. I would, because I'd be worried…		x	
SP21	If that was absolutely...yeah, I would do that, no problem, if that was what was necessary.		x	
SP22	Well I try and make sure that I come every six months and I guess…		x	
SP23	Possibly, but I suppose that I would leave that up to the dentist to decide. It's not something I would know. Yeah, yeah, hmm.		x	
SP24	Yeah, yes.		x	
SCOTLAND SUMMARY		1 (4%)	22 (92%)	1 (4%)

Table 5.12 Views on visiting the dentist every 3 to 6 months if high risk- Oman (B= barrier; F= facilitator; E= equivocal response)

COM-B/ TDF CODING Patient preference/motivation Physical opportunity / resource issue for practitioners **CODING SUMMARY** Lack of patient attendance is an opportunity barrier				
Question: Would be happy to visit the dentist for a mouth cancer check more often (3-6 months) if dentist told you were at higher risk?				
ID	**Responses**	**B**	**F**	**E**
OP1	Yes I can come- as a doctor said every 3 to 6 month, or once yearly no problem as long as I don't get the disease and it spread out.		x	
OP2	I will come, no problem		x	
OP3	Yes I agree		x	
OP4	I don't mind, we need to follow up if we are in high risk and vies versa.		x	
OP5	I will come , I have it in my genes , the reasons is there , my percentage is 100% , I have to stop smoking and drinking this might reduce the percentage about 75 %,		x	
OP6	Yes I would visit, its for me		x	
OP7	That's correct, as long as I am in low risk then its fine.		x	
OP8	If the person is honest with himself and have a proper lifestyle and I think he will come to clinic. As cancer is dangerous disease and treatment is expensive, so person must come.		x	

OP9	Its excellent, I think it motivate us to take care of yourself.		x	
OP10	I …will accept that for sure.		x	
OP11	I think if the person in low category 12 month is too far. I see three to six months also too far for high risk patient it should be shorter duration for both categories.			x
OP12	Every six months I will come, every three months I will not come.	x		
OP13	Yes, I feel comfortable.		x	
OP14	Yeah. I'd prefer not to visit the doctor every six months.			x
OP15	Definitely, everyone will come. Yes, and the drinkers [18:04] they'll come		x	
OP16	Yes, I feel it is very nice and because now in our country or in our primary health careit is crowded, they don't have appointments […] but if they know they will do this cancer check-up or like that, they will be happy […]		x	
OP17	Yes, I'm happy because to checking every three or five/four months is, I'm very happy.		x	
OP18	Okay. Yes, it's good.		x	
OP19	Sure. I should. It's not about being happy or not happy. I should do it and it's something I have to do until they make sure I am healthy.		x	
OP20	Yes, I do agree with that also, because as the risk becomes higher then you need to, what I mean, appear more frequently.		x	
OP21	Yeah, it's okay also. Because I have and then must do check-up and then they know what we'll do.		x	
OP22	Of course. Because I would like to feel like...how can I say? To feel that the progressive treatment is better and the condition is getting better, you know. So I think, yeah.		x	
OP23	Yeah, of course, but I think it is long, long time. Yeah, I think it is- it must be more short. Maybe one to two month. I think it will be comfortable for the patient, yeah, to make sure about the cancer.		x	
OP24	Yeah, I'm fine, yeah, as long as it give me...give me like a report or something about my health, I'm fine, yeah. I'm happy to...to get.		x	
OMAN SUMMARY		1 (4%)	21 (88%)	2 (8%)

It is clear from the tables above that patients from both settings have no objection in principle to attending the dental practice every 3 to 6 months if scored as high risk.

Failure to attend can be problem for preventive appointments / check-ups in general, and evidence for frequency of recall is somewhat equivocal - so more research is needed to see if stratification of patients by risk is feasible and appropriate. A similar question was asked about less frequent check-up visits for low risk.

Table 5.13 Patient views on visiting the oral health care setting every 12 months or 2 years if low risk; Scotland (B= barrier; F= facilitator; E= equivocal response)

COM-B/ TDF CODING

Patient preference/motivation

Physical opportunity / resource issue for practitioners

CODING SUMMARY

Lack of patient willingness is an opportunity barrier as in places a burden on services so that high risk patients cannot be targeted

Question: Would be happy to visit the dentist for a mouth cancer check less often (12 months or 2 years) if dentist told you were considered at low risk?

ID	Responses	B	F	E
SP1	Still come in because you still need to look after your teeth.	x		
SP2	Yeah.		x	
SP3	Yes, no problem, six months, a year, okay.		x	
SP4	Yeah, maybe less than that, once in a year.		x	
SP5	Less, I would say. Once a year. Aye.		x	
SP6	[Patient not asked the question]			x
SP7	Once A year.		x	
SP8	I'd probably just come in as normal routine, because if there wasn't really a higher chance then I'd just come on a basic routine, so I would.	x		
SP9	Maybe once a year if it's low-risk.		x	
SP10	I may come once in a year, it depend, if I have to, I will come, if I don't I will not come, I will not.		x	
SP11	Aye, if I'm low, aye.		x	
SP12	I should actually visit the dentist more often			x

	anyway in a year, but…I would go more often I think if I had any problems.			
SP13	Oh no, I think I coming every six months. Well I only have hardly any teeth but my granddaughters, and my daughter, and my grandsons all come to this practice, and they've got perfect teeth, and I think if they come at least once a year, but I think if they're maybe at a wee bit of risk, every six month's a better time.	x		
SP14	Yeah, I think it's six-monthly anyway, check-ups, so I think they could do it then, couldn't they?			x
SP15	I'd want to continue coming every six months.	x		
SP16	Yeah, less often. Yeah, once a year would be fine, yeah.		x	
SP17	I don't think life works like that; I don't think if somebody tells you that you're low risk for something that you don't need to keep getting checked – that's not how it works. So I think most people know that if you're at low risk it might mean you're not at risk of getting it but it's not a guarantee.	x		
SP18	Then I still come for my check up every six months, theoretically.	x		
SP19	Yeah. I think that's…I mean, I think that's the same with most other cancers. You know, it's…like, if there's a risk then…or there's no risk […]			x
SP20	If I was low risk I would just do what I usually do, like the twice a year.	x		
SP21	Yeah. I mean, I would have to trust the dentist, there, them saying to me, you'd be better to have it done every whatever it is. If it's a yearly, that's fine, I would trust the dentist to do that, you know, I wouldn't be able to maybe make that decision.		x	
SP22	Well normally you come for check-ups every six months to a year, so I think if they just did it as part of your normal check-up then that's fine. And I suppose they're the experts, and if you're at low risk then perhaps they don't need to do it as often.		x	
SP23	I still prefer to come to the dentist twice a year at least, because…I don't know, I just think it's good to keep, for me, anyway, to keep coming, to keep familiar with being in the dentist's chair, you know, because I get very nervous about it.	x		
SP24	No, I prefer coming every six months to get the check-up.	x		
SCOTLAND SUMMARY		9 (38%)	11 (46%)	4 (16%)

Table 5.14 Patient views on visiting the oral health care setting every 12 months or 2 years if low risk; Oman (B= barrier; F= facilitator; E= equivocal response)

COM-B/ TDF CODING

Patient preference/motivation

Physical opportunity / resource issue for practitioners

CODING SUMMARY

Lack of patient willingness is an opportunity barrier as in places a burden on services so that high risk patients cannot be targeted

Question: Would be happy to visit the dentist for a mouth cancer check less often (12 months or 2 years) if dentist told you were considered at low risk?

ID	Responses	B	F	E
OP1	Yes I can come. as a doctor said every 3 to 6 month, or once yearly no problem as long as I don't get the disease and it spread out.		x	
OP2	I would like to come, but I prefer every 6 months.	x		
OP3	Yes- because I will detect the disease early and avoid any thing may happened and I can treat myself early by any easy way they will give me as treatment to protect myself from it.			x
OP4	I don't mind, we need to follow up if we are in high risk and vice versa.		x	
OP5	It is ok, I might not come. I will be relaxed cause I don't have it, but if I have high percentage I will come.		x	
OP6	Yeah but it isn't just for cancer, it's for prevention. so if I don't have to visit the doctor for cancer it is understandable but that doesn't mean that I have to stop visiting the doctor, additionally I have to visit the clinic every couple of months.	x		
OP7	As long as I don't have risk factors I can come every 24 months.		x	
OP8	It's a good idea. I will come.		x	
OP9	Its excellent, I think it motivate us to take care of yourself.		x	
OP10	Yes I will come, …. I would be happy		x	
OP11	I think if the person in low category 12 month is too far. I see three to six months also too far for high risk patient it should be shorter duration for both categories.			x
OP12	Check up...cancer check-up, no problem for me, I will come. Twice yearly I will not come, yearly...		x	

OP13	I feel comfortable, it's okay, because a long time between visit and visit. So we have another life outside clinic, it's okay for me. It depend the point.		x	
OP14	Yes.		x	
OP15	Yes, sure.		x	
OP16	Yes.		x	
OP17	No, I'm not happy because it's too long. Well but I can't see another way, yes, because 12 months is too long.	x		
OP18	Okay. Yes, it's good.		x	
OP19	Yeah, I think once a year is the least that each person should do it. You know, I need a check-up just like anything…everything else like medical check-up. If it's not twice a year, it should be once a year, but not every two years as I think it's a long period of time.			x
OP20	Yes, that's fine. I think if I am in low risk, annually, once, that's fine. Yeah.		x	
OP21	It's okay no problem, just to prevent.		x	
OP22	Yes, I would be happy.		x	
OP23	But easy to forget the appointment in 12 month, I think. It's a good, great.		x	
OP24	Yeah, it's okay as well, but maybe it's better to...to do regular check, and less...lesser duration...less than 12 months. Every six month will be better.	x		
OMAN SUMMARY		4 (17%)	17 (71%)	3 (12%)

It is clear from Tables 13 and 14 above that patients from Scotland have more concern about waiting longer between appointments (professionals were similarly concerned). In Oman the view was more to trust the dentist and come less frequently which is an enabler to free up time and resources; again, more research is needed to see if stratification of patients by risk is feasible and appropriate.

5.4.7 Barriers / Facilitators to being Checked by Opposite Gender OHCPs

The social norm (social opportunity element) was also explored with respect to being examined by professionals of the opposite gender. As might be expected, Scottish dental patients had no objection to be treated and /or screened by any oral health professional of opposite gender as long as they were professionally competent:

"Oh yes, I'd understand that. For this country, fine, but everybody has their own cultures. So…" (SP7)

"No, I wouldn't bother. Male or female, it doesn't bother me"(SP 11)

"No problem. Female, no problem, okay" (SP 19)

"As long as they're professional I don't mind at all. It's… Yeah, it doesn't bother me" (SP24)

Oman in contrast has a culturally oriented health care system, whereby patient and health care provider relationships are based on mutuality of predetermined social norms which are essential for overall quality patient care. Culturally and socially influenced norms affect all oral health care dental practitioners' initiatives and behaviours including their performance of standards of screening practice. Thus, there was a mixed response; patients on the whole felt a same-gender examination would be preferable if possible. Below are some quoted responses from Omani patients:

"Because relating to our culture I don't like any male to touch my neck area" (SP 23)

"We are as a conservative Islamic country. we are in touch with our religion, especially those villages in Aldakliah not in the coast " (OP5)

"If the dentist can palpate my head at the top my head cover its fine, but if he needs to expose my neck area and head, no, if my head is exposed its difficult. "(OP5)

"I think what is good for her health she has the right to do it. May be a female dentist will not be there but I prefer a female dentist" (OP10)

"Well, in medication we should not bring our religions in a medical area, or our culture in with a doctor. Medication is something different than culture or religion; and it is a part of religion and a part of culture, and a part of morality as well" (OP 14)

It is important to ask such questions. Whilst these interviews were with a population in an Islamic country, dental care worldwide employs a diverse workforce and serves patients from culturally diverse backgrounds. Such barriers as observed here are rarely addressed fully in trials, systematic reviews or guidelines.

5.5 Discussion

High oral health awareness and knowledge about oral cancer may facilitate early detection of lesions by practitioners in that patients will attend practice for checks and be amenable to checks being carried out, and discussions about social risk factors. This study highlighted a lack of awareness among the participants mainly in Oman, but generally showed a higher awareness among patients in Scotland. This is in agreement with findings in other studies which have investigated public awareness in different countries such as UK, India, Australia, Malaysia, and Turkey (Peker et al., 2010; Ghani et al., 2013; Formosa et al., 2015; Joseph et al., 2016; Conway and Purkayastha, 2018).

In Oman, lack of awareness about oral cancer may be partially explained by the low incidence of the disease (Chapter 1). Lack of awarenesss of oral cancer has previously been linked to low population incidence of the disease (Warnakulasuriya et al., 1999).

The media profile of mouth cancer may also be a differential. In Oman, mass media focus on other types of cancer which have a higher level of incidence in the country, such as thyroid and breast cancer (MOH, 2019). In Scotland, patients reported that the main sources of their awareness and knowledge about oral cancer was the media (e.g. television, newspapers / magazines) which is similar to reports from other studies conducted in other countries such as UK and USA (Warnakulasuriya et al., 1999; West et al., 2006; Choi et al., 2008).

It was interesting to find out that patients in both countries were generally unaware that screening can be part of their treatment or the OHCPs' role. Other responses indicated that many patients are unaware if / whether oral cancer screening is taking place. While the COE might be adopted as a standard of care in dental settings in Scotland, like other countries (Gustavo et al, 2005), the practice is not communicated efficiently with the patients. Similar finding were also reported whereby dentists in the US were found not to be exchanging information with the patients while performing a COE (Choi et al., 2008).

Professionals have a role to play in making sure patients consent to and are aware of the benefits of a COE (see Chapter 4). Many studies have assessed the screening practice for oral cavity cancer among oral health care professionals (Seoane-Lestón et al., 2010; Suresan and Vijay Kumar, 2012) and unfortunately reported lack of confidence and / or up-to-date knowledge about oral cancer screening which may be filtering through to patients.

There were few barriers to being examined, but some Omani had issues with regard to gender. Data on cultural issues in the dental team-patient relationship have been slow to emerge (Butani et al., 2008). There are understandings of needs of Islamic patients in nursing (Blankinship, 2018) and some work in medicine speaks of 'cultural competencies' (Ezenkwele and Roodsari, 2013); various studies have described, for example, how patients prefer ethnically and dialectically matched dental providers (Wang, 2007). Attum and Shamoom cover a number of current issues affecting Muslim patients and conclude that "During a physical exam, it is desirable to have the health care professional of the same sex." (Attum and Shamoom, 2020).

In Scotland there was less of a barrier or 'taboo' in using the term cancer when conducting checks than in Oman. Previous work for example in Iran shows this is a 'taboo' subject, with important negative effects (Zamanzadeh et al., 2013). Professionals did, however, seem to thus overestimate the extent to which Scottish patients would see this as problematic. This could be a topic for intervention (see Chapter 6).

Risk tools have been developed for many different types of cancer such as breast, lung, and prostate. Patients in this study were asked questions, based on a prototype risk prediction tool developed by the INHANCE network, to identify barriers and facilitators towards potential implementation in primary health care dental settings. Patients and oral health care professionals (Chapter 4) broadly reported positively toward such a tool. There was some question of whether using a tool electronically (i.e. as in an 'app' format) was less desirable than a face-to-face assessment. This raises resources / time issues for professionals (see Chapter 4). Future research is needed to take this further and assess feasibility and effectiveness of this tool.

5.5.1 Strength and Limitations

Strength of this study are various: 1) the first qualitative cross-cultural study conducted over two different systems to compare views and experiences of dental patients attending primary health care settings in relation to oral cavity cancer early detection / screening; 2) first empirical investigation guided by theoretical domain framework to identify factors (barriers / facilitators) associated with dentist behaviour in areas of oral cancer screening practice based on patients' views; 3) use of a bilingual interview tool with dental patients focused on their clinical experiences with oral health care professionals practicing at

primary health care dental setting; 4) consistency of research interview methods both in Scotland and in Oman.

This was a relatively novel use of these frameworks. In effect, patient wishes serve as social and / or resource enablers / barriers for the implementation of evidence-based behaviour by OHCPs. The main TDF domains emerging here, as designed, were thus to do with patient knowledge, their motivations towards the interactions in question, and social influences such as culture and gender. The environmental context and resources (physical opportunity in the COM-B model) for dental professionals are affected by patients' willingness, for example, to attend practice more or less frequently. The COE and communication regarding cancer and risk are socially constrained (or otherwise) by patient preference and expectation. Patient beliefs about consequences (reflective motivation in the COM-B) is important in relation to their engagement in risk screening and subsequent targeted recall. In summary, the TDF / COM-B frameworks serve to ensure a range of questions are asked that cover potential influences on behaviour. Here this was limited to a smaller set of domains, as the behaviours in question are primarily specified for the professional teams to engage in. This study is adjunctive to that in Chapter 4. Thus, in Chapter 6 the synthesis takes place of the evidence-base review together with views from professionals and patients alike.

As with any study's methods, the mixed-data questionnaire utilized in this study has strengths and weaknesses. Examples of relative strengths include the use of open questions which facilitates the generation of subject viewpoints of greater depth, allows the researcher to gain deeper insights, and adds value and authentication to related themes in the analysis phase (Bryman, 2008; Creswell, 2009). Weaknesses (disadvantages) of open-ended questions include: the risk of generation of unwanted data; the possibility of a diversion in interview focus; possible increased survey fatigue; being time and energy consuming; mandating equal attention for all participants; and, requiring bilingual translation, particularly for participants who speak English as a second language. Fixed response questions were utilised in part in responses to this, serving to: facilitate shorter interviews; ease broad comparisons between groups; check the 'sense' of open-ended responses against broad orientations. However,they do suffer from a general difficulty in interpreting the meaning of responses, and they limit reflection on experiences (Bryman, 2008; Creswell, 2009).

5.6 Conclusion

In conclusion, patients are open to some aspects of comprehensive risk profiling and opportunistic screening in the dental primary care setting. They have little current awareness of what the dentist should and / or could do in this respect. Barriers include some culturally sensitive issues in Oman around gender-matched intra-and extra-oral examinations. In Scotland, the perceived unwillingness to talk openly about cancer appears overstated, based on this small set of patient interviews. Risk assessment was again received better in Scotland due to risk behaviours being culturally sensitive in Oman. Chapter 6 brings this together with the overview and the professional interviews to discuss recommendations and interventions. The models used here allow for targeting intervention domains based on thematic findings of barriers (Michie et al., 2014).

Chapter 6: Discussion and Conclusion

6.1 Introduction

This chapter discusses the findings of the thesis – synthesising the results across the systematic overview and qualitative studies chapters (6.2). A comparison of the findings between Oman and Scotland will then be drawn out (6.3), followed by a section on the strengths and limitations of the thesis approaches undertaken (6.4). The thesis findings will be interpreted in terms of recommendations for practice (including developing a potential intervention), for guidelines and policy, and for further research (6.5). Finally, the thesis will end with a conclusion section (6.6).

6.2 Synthesis of Thesis Findings

Evidence based dentistry and practice were at the centre of this thesis. The main research aims were to identify best practice in relation to early detection / screening of oral cavity cancer in primary care dental settings, and then to explore the barriers and facilitators to implementation from both oral health care professionals' and patients' perspectives.

Oral cavity cancer survival is poor but there has been limited improvement in recent decades (Public Health Scotland, 2020). Advanced stage at presentation of these cancers is associated with greater morbidity and mortality (Seone et al., 2016). Development and implementation of clinical guidelines of best practice in the early detection / screening for oral cavity cancer in primary care dental practices has an important potential role in contributing to addressing these challenges. These clinical guidelines are developed statements and recommendations that guide the health care professionals to make the correct clinical decisions. Research indicates that clinical guidelines provide organisation, guidance, and support and can fill crucial gaps in the evidence base when the research evidence is sparse (Fischer et al., 2016). Despite the existence of a high number of clinical guidelines, their use is reported to be slow, unapplied, and neglected (Fischer et al., 2016). Therefore, it is seen as essential to develop implementation strategies by identifying and overcoming the barriers that affect the implementation of clinical guidelines and improve adherence and sustainability to them (Knops et al., 2010). A scoping review by Fischer and colleagues (2016) was conducted to categorize the barriers to implementation of clinical guidelines. It identified the barriers, interventions and strategies required for guidelines implementation. The review lists a number of barriers at different levels that hamper the implementation of clinical guidelines - for example, personal factors such as physician knowledge and attitudes; guidelines factors such as lack of evidence, poor method, lack of applicability; external factors such as lack of collaboration, lack of social and clinical norms, and lack of resources. The review also outlines a

number of strategies related to overcoming these barriers – for example, barriers related to personal factors could be solved by continuing professional development education programmes; barriers related to guideline dissemination and uptake could be solved using different platforms and making them easier to access and use; and barriers related to external factors could be overcome by improvements of organisation of care (Fischer et al., 2016).

In this thesis it was essential to identify, understand and bridge any gaps between the evidence base, clinical guideline recommendations, and implementation barriers in primary dental care settings in relation to early detection / screening of OCC. This needed to include understanding of current knowledge, views, and practices both from an OHCP and patient perspective – and how these relate to best practice.

The thesis research involved a systematic overview of the evidence-base for the early detection / screening of oral cavity cancer to identify best practice in the primary dental care setting; followed by qualitative research studies involving oral health care professionals and patients in Oman and Scotland to explore implementation factors for this best practice.

The thesis developed a taxonomy of aspects of this best practice for early detection / screening of oral cavity cancer in primary dental care settings, which was used as a framework to assess the evidence-base: the effectiveness of the conventional oral examination (COE); whether the COE should differ based on risk or be targeted or delivered on a universal, all-patient basis; the frequency / recall interval for the COE; and the role and effectiveness of Adjunct Tools to the COE.

The systematic overview (Chapter 3) found that there was limited evidence of the effectiveness of the COE for early detection / screening of oral cavity cancer. There was a tendency for high quality systematic reviews to suggest the COE was more effective in high prevalence populations and also when performed in high risk individuals (defined as those who use tobacco and consume alcohol). There was not enough evidence to support only doing COE or doing a more detailed and focused COE in high risk dental patients. While there was a lack of evidence per se on the effectiveness of opportunistic screening, this was the approach broadly concluded in the high quality systematic reviews and clinical guidelines. There was a limited evidence-base, but some clinical guideline support was identified for a risk-based recall interval for conducting a COE based on assessed oral cavity cancer risks (3-6 months for patients at high risk, and 1-2 years for those at low risk). There was no evidence for the effectiveness or role of adjunct technologies to the COE in the early detection / screening of oral cavity cancer.

The qualitative study with oral health care professionals (OHCPs) found that COEs were generally routinely performed during dental check-ups, although there were some variations in clinical practice with regard to how COEs were performed in both Oman and Scotland (Chapter 4). This contrasted with a number of other studies in the literature where OHCPs often did not see COE for

early detection / screening of OCC as being part of their routine dental check-ups (Canto et al., 2002; Horowitz et al., 2002; Choi et al., 2008). Adjunct methods were not used – although in Oman this was reported to be due to a lack of the availability of the technologies rather than knowledge of the lack of evidence for them. There was concordance in both countries about the role of COE opportunistically – rather than as a targeted approach or screening programme. However, while there was a reluctance by the OHCPs to label this as a specific COE for early detection of oral cavity cancer, they were prepared to consider the idea of using a risk prediction / assessment tool related to the delivery of the COE.

OHCPs in both countries were more supportive of reducing the recall interval for COE for patients identified as high risk and less supportive of extending the recall interval for COE for patients identified at lower risk. Moreover the discussions on recall interval became more focused on recalling patients for review when a OPMD or suspicious lesion (such as an ulcer) was initially detected and ahead of referral. This is in-line with other sources of information on dentists' views on recall interval in relation to oral cancer, such as the British Dental Association (BDA) Scotland branch who produced a report strongly advocating against any risk-based recall interval (BDA, 2018). This position was based on their clinical opinion rather than scientific evidence or data. More understanding of the barriers and facilitators for risk-based recall intervals is required, especially as it is increasingly proposed in the redesign of dental services, including in the NHS in Scotland (BDA-Scotland, 2018) and England (PHE, 2017).

Reading across to patients' views and experiences in relation to early detection / screening of oral cancer (Chapter 5), there were differences in perspectives between patients and oral health care professionals. While the OHCPs were concerned about using the term "oral cancer" when performing a COE, patients, particularly those in Scotland, did not seem to have a problem with it. This finding goes along with patients not realising that a COE for early detection / screening of oral cancer was routinely performed when they attended for a dental check-up. Dental patients interviewed seemed to be happy to be assessed for their oral cancer risk, which agrees with recent trial research on communicating risk to dental patients (Harris et al., 2020). The patients indicated that they would be willing to consider attending more frequently (3-6 months) if they were identified as being in a high risk group, although they were more reluctant (and less forthcoming) on agreeing that they would attend less often if they were identified at low risk.

6.3 Comparing Findings in Oman and Scotland

Chapters 4 and 5 outlined various reported activities and viewpoints of OHCPs in Oman and Scotland with regards to the COE and associated practices. Examinations were broadly enacted by OHCPs. The interview with the OHCPs in Oman indicated challenges including: hierarchical

structure in the dental workforce where dental hygienists were not performing COE as it was considered the role of dentists; the absence of related clinical guidelines; lack of training programmes; lack of patients' overall awareness that COE is expected as part of the professional duties of the OHCPs for early detection / screening for OCC. This suggests some capability issues (knowledge-based) that might be addressed through education / guidance or training (Welke et al., 2003). Social influence from patients might facilitate COE, but only if patient awareness itself is addressed. We know that patients are less likely to receive intra- and extra-oral examinations if they are from less educated / low income groups (Gupta et al., 2019).

In Scotland, there was a reported lack of awareness among patients that they were receiving a COE for early detection / screening of oral cavity cancer – despite OHCPs saying they were doing in. Barriers to implementing COE from the professional viewpoint were more often related to time / opportunity, which has been similarly reported in numerous health related studies (Gott et al., 2004; Légaré et al., 2008; Harding et al., 2014). It is known that in dentistry in the UK, preventive care suffers implementation barriers due to the linking of remuneration to treatment items (Birch, 1988) and also to the way dentists are trained (Glick et al., 2012).

Building on the above, effective implementation requires consideration of factors beyond simple communication / guidance. Some form of enablement through the context of practice is needed and indeed has been documented before (Grytten, 2005). This is in line with the behaviour change theories applied in Chapters 4 and 5. There were no strong skill-based barriers in the capability of OHCPs in Oman or Scotland to perform oral cancer screening on their primary care patients, but efforts to get OHCPs to engage with COE linked to risk assessment are likely to be less than fully successful until a comprehensive process is clearly specified and remunerated.

Optimising the role of the dental team is one way of potentially getting over the professional role barriers (Brocklehurst and Tickle, 2011) although further study is needed to determine public perceptions of the professional preventive role of dental team members in relation to oral diseases (Crigger et al., 2009). It is a finding of this study of COE that the long called-for shift to a culture of preventive practice including environmental restructuring according to research (Steele, 2009) would be the major enabler / facilitator, rather than training in techniques per se. It has been previously reported that OHCP uptake of attending to (reading) and undertaking training towards clinical guidelines is poor, but this can be inferred to be a symptom of lack of evidence-based environment / ethos rather than the 'root cause' (Witton and Moles, 2013).

Patient willingness to accept checking for OCC was generally forthcoming in both settings. However, a differential appeared in terms of the use of the term cancer in conjunction with the examination (i.e. explaining to patients what is going on and why). Omani patients were far more equivocal as to whether this would be acceptable or would make them uneasy / fearful (Table 5.8).

This aversion to explicitly acknowledging that there is a risk of OCC has been referred to in generic terms before as the 'ostrich strategy' and observed across primary care prevention (Moreno-Peral et al., 2015).

There is no easy way to reduce patient anxiety with regards to cancer, but a patient-centred approach based on shared decision-making is key (Calderón et al., 2011). Patients in both countries broadly welcomed the idea of having a risk score or a risk-level categorisation based on social history / modifiable risk factors. However, this was subject to some concerns about probing for alcohol in Oman - drinking alcohol is religiously forbidden and therefore it is a sensitive subject to be discussed. In Scotland, the barrier is more related to the socially normative acceptability of alcohol use. Some of the professionals highlighted the lack of awareness programmes or campaigns about the link between drinking alcohol and throat / mouth cancer in the same way that smoking is campaigned against. The different level of awareness of smoking versus alcohol risk is a worldwide problem (Yamsani et al., 2014).

The combination of alcohol and smoking is a vital synergistic risk (Hashibe et al., 2009) and hence the management of patients must address lifestyles that contribute to an increased risk of oral cancer (Speight et al., 2010). However, alcohol drinking in the Eastern hemisphere is socially normative and drives much economic activity. Awareness campaigns that links mouth / throat cancer to drinking alcohol are much less well supported than those for smoking, which while still prevalent is socially less acceptable and, for example is banned in enclosed public spaces in the UK. Research into how best to raise awareness of alcohol risk, and combined risk, is needed.

If deemed at risk, patients in both settings said they would attend for check-ups, which could be an important driver for conducting clinical oral examinations as well as receiving prevention interventions. The assessing of risk is embedded in social history taking but scoring / classifying in this way again needs more work on implementation (e.g. patients preferred a face-to-face history taking but this has time / resource implications in practice. The converse was not true - both professionals and patients were wary of less frequent checks for those deemed at low risk.

There was a lack of evidence in the systematic reviews for the use of Adjunct Tools to support the COE in primary dental care (Patton, Epstein and Kerr, 2008; Rashid and Warnakulasuriya, 2015). In Scotland, whilst resource issues (training needs) were cited, there was some understanding of this evidence base, inhibiting use. This was less clear in Oman, where lack of use of Adjunct Tools was reportedly more opportunity-based (inferring a knowledge gap).

6.4 Strengths and Limitations

The strengths and limitations of the whole thesis will be discussed in turn here. Detailed methodological strengths and limitations are included at the end of each study chapter (Sections 3.7, 3.8, 4.9.1, and 5.5.1).

Strengths

There was an initial intention to test the implementation of an intervention for early detection / screening of oral cavity cancer in primary dental care. However, at the outset of the thesis, despite the seeming wealth of systematic reviews and clinical guidelines in the area, there was a lack of clarity on best practice for oral health care professionals. Therefore, a comprehensive systematic overview approach was taken to distil the evidence. A novel methodological approach was developed to bring together both systematic reviews and clinical guidelines. This overview included i) a systematic search of multiple databases including grey literatures sources to find relevant systematic reviews and clinical guidelines; ii) thorough quality appraisal of systematic reviews and clinical guidelines using critical appraisal tools and multiple assessors; and iii) a thematic narrative synthesis based on quality and recency of publications. The overview methodology followed and adapted best practice from systematic reviews (McKenzie, 2018). Assessing the thesis overview methods itself against the AMSTAR and ROBIS tools (Perry et al., 2017; Banzi et al., 2018) shows a level of high quality and low risk of bias.

Following the systematic overview, qualitative in-depth interviews with oral health care professionals were conducted following a semi-structured approach based on findings emerging from the ongoing overview synthesis. The data from these interviews were comprehensively analysed using psychological theory (COM-B and TDF) (Michie et al., 2014) to understand the barriers and facilitators from a OHCP perspective to implementing best practice interventions. This was then complemented by similar in-depth qualitative interviews with patients analysed again via psychological theory. Patients' views are essential to roundly understand the challenge of implementing change in health care practice (Vahdat et al., 2014; Mohammed et al., 2016).

Further, this thesis is the first qualitative cross-cultural study conducted over two different countries' health care systems (Oman and Scotland) to compare views of OHCPs and dental patients in relation to early detection / screening. The qualitative approach was the best method to use for the studies because it helped to explore and to understand the behaviour of both OHCPS and the patients in relation to OCC early detection / screening (Creswell and Poth, 2016). Further, this approach enabled new understanding, revealing differences of views and behaviours between OHCPs and patients - including, for example, risk prediction and talking about oral cancer (Hulme, 2007). In addition, this approach helped the researcher to have a deeper insight into understanding

the behaviour and the knowledge of the OHCPs and patients, using an up-to-date model of behaviour change – the Behaviour Change Wheel (BCW) (Michie et al., 2014). This approach helped the researcher to be creative in data analysis, for instance, thematic analysis was applied based on TDF /COM-B frameworks (Hulme, 2007). Moreover, the thesis is the first for its empirical investigation procedures guided by the theoretical domain framework to identify factors (barriers / facilitators) associated with dentist behaviour in areas of oral cancer screening practice based on patients' views. Additionally, the thesis involved a bilingual interview tool (Arabic & English) with dental patients focused on their clinical experiences with oral health care professionals practicing at primary health care dental setting – enabling deep insights into cross-country and culture comparisons between Oman and Scotland.

Limitations

The main limitation of the systematic overview was not necessarily in the methods employed, which followed standard guidelines for systematic reviews (Cochrane Collaboration, 2020), but was in the limited availability of high quality data within the systematic reviews or referred to within the clinical guidelines. On one hand, at the outset, it looked as though there were multiple sources of evidence, however, when they were reviewed thoroughly, the original source studies and trials which the systematic reviews had included were limited both in number and quality. An alternative approach would have been to have reviewed and updated these original systematic reviews. However, this would not have been feasible in the time-scales and would have limited the review to one dimension of the clinical practice of early detection/screening for oral cancer e.g. on adjunct methods. The overview approach enabled a broader perspective to be taken – but the limitation of the underlying evidence-base holds.

With respect to the inherit limitations common with qualitative studies, this thesis was not exceptional. Purposive samples are limited by the thematic results being a reconstruction of the subjective experiences and perceptions of a small number of participants, working within the context of a specific situation and location. There were some limitations on questions on recall interval for undertaking COE and basing the recall frequency on a risk assessment were often responded to in relation to recalling OPMD lesions before referring for a specialist opinion.

Moreover, the researcher's subjective judgments as a OHCP and personal ideas relating to the need for OHCPs to implement improved methods of detecting, screening and preventing OCC might possibly bias some of the results and conclusions. However, this was mitigated as much as possible by rigorous objective coding and systematic thematic analysis.

6.5 Recommendations

This section discusses recommendations that arise from the thesis findings. Firstly, these recommendations are described in relation to practice – in terms of developing clinical behaviour-based interventions, then in relation to clinical guidelines and policy, and finally recommendations for further research are set out.

6.5.1 Towards Recommendations for Clinical Behaviour-based Interventions

Chapters 4 and 5 explored barriers that affect implementation as a first step to improve adherence to evidence-based early detection / screening of OCC (Knops et al., 2010) through the theoretical lens of the Behaviour Change Wheel and its antecedent frame of theoretical domains (Atkins et al., 2017). This identified a number of barriers which might be addressed to improve care. Table (6.1) shows the generic intervention functions indicated guide based on the model.

Table 6.1 General intervention guide based on behaviour change wheel domains (Michie et al., 2014).

Type of intervention	**Capability**		**Opportunity**		**Motivation**	
	Physical	Psychological	Physical	Social	Automatic	Reflective
Education		√				√
Persuasion					√	√
Incentivisation					√	√
Coercion					√	√
Training	√	√				
Restriction			√	√		
Environmental restructuring			√	√	√	
Modelling					√	
Enablement	√	√	√	√	√	

The ticks indicate the type of intervention required to address the specific capability, opportunity, and motivation domain.

Broadly speaking, as expected, education and training are indicated for knowledge and skill issues (and to help with judgement / reasoning i.e. reflective motivation), but opportunity barriers have to be targeted for enablement at the environmental level (such as providing resources or training).

In terms of the COE theme, there does not appear to be a technical issue. Basic skills (physical capability) of the OCHPs in Scotland and Oman when conducting COE appeared similar, though there was some variation in descriptions of COE (e.g. in examining aspects of the tongue; Uti and Fashina, 2006) which might provide a focus for refresher training and / or guidance (Fischer et al., 2016), though it is known that guidance itself has barriers to uptake (Kredo et al., 2018).

In Scotland, physical opportunity barriers to COE (time / cost, and resources) were the limiting factors cited from the professional standpoint. The BCW model also refers to higher level policy functions (Michie et al., 2014) such as legislation or regulatory change, and service provision, and meaningful progress in opportunistic screening (incorporating risk / social history- see below) is likely to require some reconfiguration at this 'macro' level. This is reflected in wider studies on opportunistic behaviour change interventions showing workload and clinical environment issues have to be overcome to support uptake (Keyworth et al., 2019). In Oman, professionals faced less resource barriers as the Ministry would provide these, but there was some sense that this was a 'dentist only' role, which could be targeted.

Patients in Oman were especially unaware that screening could / should be part of dental care. Patients being unaware of why COE is being carried out might be a barrier and again wider level policy functions could help such as communication / awareness campaigns. There were more 'taboos' in terms of using the term cancer, (and social history taking with regards to alcohol) in Oman, but in general there are no major social influence / opportunity barriers for professionals in terms of patient factors (professionals somewhat overestimated the extent to which Scottish patients would see cancer discussions as problematic). Attempts to increase patient awareness / acceptance (education / training interventions) of course exist (more so in Scotland - in Oman the media focuses on higher incident diseases) and could be a driver for care through increased expectation (Paudyal et al., 2014).

In terms of targeting, professionals in both countries largely carried out COE for all as indicated in Chapter 3 to be optimal. Evidence also suggests the use of risk assessment, and in both countries, professionals and patients reacted largely positively when asked about the prototype risk prediction tool developed by the INHANCE network (Lee et al., 2020). This itself is an enabling intervention. An important issue to address is how / where the patient-tool interface would best be deployed, so that efficiency can be maintained, and

how best to communicate risk. Risk communication in relation to dental check-ups has begun to receive some recent research attention - albeit not specifically related to oral cancer risk (Harris *et al.*, 2020).

Whilst evidence is equivocal, current UK guidance (NICE, 2004a) is that the interval between oral health checks should be patient-specific, tailored to need and risk assessment. Interestingly, patients were happy to return for more frequent check-ups based on high risk, but less so to attend practice infrequently if deemed low risk. Getting patients to adhere to recommendations from health professionals is a known issue (WHO, 2003) and the small dataset in this study indicates 'low risk' patients may want to continue regular check-up appointments as usual rather than be 'triaged' to less frequent visits. Professionals were similarly wary of longer times between checks (inferring missed or late detection / diagnosis risk). Shorter intervals raised once again resource / capacity issues in Scotland.

The use of Adjunct Tools in primary dental care lacked evidence (Messadi, 2013) and their use was limited in OHCPs in both Scotland and Oman. Omani reasons were more simply about opportunity / availability. There was some more reflection and reasoning in Scotland but also some citing of resource issues such as a need for training. This does suggest some educational intervention to bring knowledge of the evidence-base up-to-date could have utility (Seoane-Lestón et al., 2010; Suresan and Vijay Kumar, 2012).

In summary, efforts in Oman could be more orientated towards dissemination of the evidence-base (education and training interventions on evidence-based COE, risk and recall) and in Scotland towards policy / practice-level efforts to enable redesign of practice towards implementing comprehensive risk based assessment and preventive practice, which could include integrating risk tools for target populations (Scottish Government, 2018).

Whilst sensitivities are likely to remain, patients themselves are generally open to comprehensive risk profiling and opportunistic screening in primary care, whilst having little current awareness of what the dentist should and / or could do in this respect.

Religious / cultural inhibitors regarding the treatment of female patients by male dentists (Attum and Shamoon, 2020), and the psycho-social barrier of talking about oral cancer (Henderson and Weisman, 2001) might also suggest social-level (e.g. role modelling)

interventions in Oman. They also indicate that studies like this, which pay attention to cross-cultural / international differences, are important.

6.5.2 Recommendations for Clinical Guidelines and Policy

The systematic overview work of this thesis is contributing to the development of the updated (4th edition) of the Public Health England guidance for prevention in dental practices – the *Delivering Better Oral Health* evidence-based toolkit (PHE, 2017) which has an oral cancer group and section (chaired by supervisor DIC). The thesis contribution to this guidance has been in terms of informing the evidence review methods and in sharing sources (clinical guidelines, systematic reviews) and in identifying best practice. The thesis findings of asserting the importance of the COE as part of a dental assessment, and linking the recall interval for the COE to risk assessment have been brought into the consideration in the revised guidance due for publication in 2021.

Despite opportunistic screening being called for and taking place in primary dental care for many years in Scotland and other countries, there seems to have been only limited improvement in survival from OCC - with limited data available to understand trends in stage of presentation / diagnosis of head and neck cancer over time (Public Health Scotland, 2020). Additionally, studies have shown that during mouth cancer awareness campaigns there is an increase of referrals of patients with "non-suspicious" lesions (Rodgers et al., 2007). Therefore, most dentists in Scotland are likely to be carrying out some form of COE, but the quality of the COE and the decision making is not necessarily optimal. Consequently, despite the raft of clinical guidelines identified in the thesis, there remains a need for a more practical clinical guideline, detailing the process of performing a conventional oral examination. This could involve a further systematic search and appraisal of the grey literature (along with further expert input) – including some of the guidelines identified in this thesis, but extending to include training manuals or continual professional development resources (including online resources), and referral guidelines, which were out with the scope of this thesis. As per the taxonomy developed in this thesis, this work should cover the details of extra- and intra-oral examination processes – including i) detailing the visual and tactile (palpation) approaches and the use of gauze and dental mirror; ii) clarifying the symptom and clinical sign checklist; iii) describing how to record and capture clinical examination information (e.g. on a "mouth map", or grid, and /

or photographic images); iv) developing appropriate referral pathways for OPMD / suspected OCC; v) identifying longer-term monitoring and recall guidance of patients with these OPMD lesions. These more practical guides with aids and advice on how to carry out the COE would support OHCPs make decisions around detecting, reviewing and referring oral potentially malignant lesions and early OCCs.

The other major challenge around the opportunistic screening model is that those from the most deprived groups, and indeed those subsequently diagnosed with oral cavity cancer, have been shown in a Scottish population data linkage analysis to be less likely to attend primary dental care in the two-year period preceding OCC diagnosis (Purkayastha et al., 2018). Therefore alternative venues for opportunistic early detection / screening of OCC could be explored in primary and community services e.g. including general medical practice.

In addition to developing further clinical guidelines, which pull together the evidence-base or best practice, it is even more important to implement already defined best practice. Implementation factors have been described in relation to taking forward a new intervention (Section 6.4.1). In relation to the policy development implications arising from this work, it could include introducing a risk-based assessment and recall interval in NHS Scotland and Oman. Such a system is already established in NHS England and in private dental insurance providers across the UK e.g. Denplan (2020). This approach is currently under review as part of the Oral Health Improvement Plan (Scottish Government, 2018). Implementing such a policy faces some of the challenges of guidance implementation, but specifically here involves addressing the financial incentives or requirements to delivering in primary dental care services, which are largely run as independent contractor businesses.

6.5.3 Recommendations for Future Research

The James Lind Alliance – which is a priority setting partnership with a significant patient and public involvement alongside professional and academic input – produced a “Top 10 Oral and Dental Health” research priorities in 2018 (James Lind Alliance Alliance). The number three priority is “What are the most effective ways of increasing early detection/diagnosis of oral cancer”. These have been adopted by the National Institute of

Health Research, which is a UK government agency which funds research into health and care. There is therefore an impetus for further research in the area of the thesis.

There have been no randomised controlled trials (RCT) of early detection / screening of oral cavity cancer undertaken in Europe. Implementing a formal screening programme has all but been ruled out as RCTs demonstrating reduced mortality / improved survival from oral cavity cancer would need to be undertaken and the National Screening Programme criteria for the viability, effectiveness, cost-effectiveness, and appropriateness of a screening programme would need to be met (PHE, 2015). There is no doubt it would be very difficult to run such a RCT in a country with low incidence of oral cavity cancer. While the review of COE effectiveness in this thesis, which largely drew on the randomised community trial in Kerala, India (albeit with some risks of bias) did show a tendency for COE to be potentially effective in high risk individuals (defined as those who smoke and consume alcohol; Warnakulasuriya et al. (2015) has set out a checklist for future studies on oral cancer screening in Europe. They proposed further research to improve opportunistic screening, including aspects of risk assessment, and future developed adjuncts. This fits in with the thesis findings which began to probe the potential for both a clearer defined "intervention" approach labelling the COE and "oral cancer screen or check-up", linking to a risk assessment (possibly via a risk prediction tool) of the major risk factors – smoking and alcohol consumption, which would also determine the recall frequency interval for the COE. A future evaluation of an early detection / screening intervention could be further developed and piloted in primary dental (and possibly medical) practice settings, involving a risk assessment, an "oral cancer check" COE, with recall / repeat intervals tailored to risk, and possibly also incorporating prevention interventions related to the risk factors (as defined by the "sister" PhD to this thesis; Mathur, 2019).

There was also modest evidence of cost-effectiveness of early detection / screening of OCC in high risk individuals in dental and medical practice settings based on modelling (Speight et al., 2006). Future clinical research needs to consider health economic evaluation. Further studies either via a simulation study or in a feasibility trial design could build on the implementation work of thesis.This could take a human factors / health care systems approach to further optimise implementation (Fischer et al., 2016).

While the thesis did not identify any solid evidence-base for the effectiveness for the role of currently-evaluated Adjunct Tools or techniques, further research in this area, to

determine if newer approaches could provide a supportive solution, would also be warranted.

6.6 Conclusions

In conclusion, high mortality and low survival rates of oral cavity cancer associated with late stage presentation remain a public health challenge. Oral health care professionals working in primary care dental settings have an important role in reducing morbidity and mortality associated with oral cancer through early detection / screening. The thesis identified pragmatic best practice that the conventional oral examination undertaken opportunistically as part of the dental check-up, which has some evidence base. There is no evidence that the COE should be undertaken differently or more intensively for patients identified at high risk (i.e. those who smoke tobacco or consume alcohol). There are some pragmatic clinical guideline recommendations that the recall interval for COE should be more frequent for those at higher risk and less frequent for those at lower risk. There is no evidence for the current role of Adjunct Tools or techniques. The qualitative interviews highlighted some important differences between patients' and OHCPs' perspectives and between Oman and Scotland. Patients were generally and reassuringly more open to talking about mouth cancer than OHCPs, patients were also open to more frequent risk-based recall intervals if identified as high risk for oral cancer, although were more reluctant to agree to a longer recall intervals if identified as having a lower risk. There were some commonalities and differences in the barriers / facilitators identified between Oman and Scotland and, should they be addressed, could support evidence implementation. In Oman there is a greater need for education and training related to oral cancer, while in Scotland there is a need for policy and health care system change to implement early detection / screening linked to risk assessment and prevention interventions in dental practice. Further work is required in Oman to address cultural sensitivities which impact on full implementation of early detection / screening interventions.

The thesis provides a good basis towards developing an intervention for early detection / screening of oral cavity cancer linked to a risk assessment and prevention interventions in primary dental care settings. Such a future intervention could have a potential to impact on reducing the morbidity and mortality from oral cancer in the community.

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Yamada, J., Shorkey, A., Barwick, M., Widger, K. and Stevens, B. J. (2015) 'The effectiveness of toolkits as knowledge translation strategies for integrating evidence into clinical care: a systematic review.' *BMJ open*, 5(4) p. e006808.

Yamsani, A., Prashanth, K. S., Kasala, E. R., Kataki, R. and Bezbaruah, B. K. (2014) 'Oral cancer awareness and knowledge in adults attending a dental hospital in Northeast India.' *Apollo Medicine*, 11(1) pp. 11–17.

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Zohoori, F. V., Shah, K., Mason, J. and Shucksmith, J. (2012) 'Identifying Factors to Improve Oral Cancer Screening Uptake: A Qualitative Study.' *PLoS ONE*, 7(10). p. e47410.

Appendices

Appendix 3.1: List of Professional Organisations/Associations

1. World Health Organization
2. Central for Disease Control and Prevention (CDC)
3. Head & Neck Cancers (Screening Guidelines)
4. American Dental Association Council
5. UK National Screening Committee
6. HealthPartners Dental Group and Clinics
7. US Preventive Services Task Force
8. American Cancer Society
9. Cancer Research UK
10. British Dental Association
11. New Zealand Guidelines Group, Ministry of Health
12. Office of Oral Health, Maryland Department of Health & Mental Hygiene.
13. Agency for Health care Research and Quality,
14. U.S. Department of Health and Human Services
15. The Royal College of Surgeons of England.
16. National Institute of Dental and Craniofacial Research.
17. Cancer care Ontario
18. National Institute for Clinical Excellence Clinical
19. British Association of Otorhinolaryngology, Head and Neck Surgery,
20. College of Dental Surgeons of British Columbia
21. Scottish Intercollegiate Guidelines Network
22. National Institute for Health and Clinical Excellence, June 2005
23. National Center for Chronic Disease Prevention and Health Promotion
24. Oral Cancer Foundation
25. National Cancer Institute
26. Scottish Dental Clinical Effectiveness Programme (SDCEP)
27. National Dental Advisory Committee (NDAC)
28. NHS Education for Scotland (NES).
29. Translation Research in a Dental Setting (TRiaDS)
30. Scottish Dental Practice Based Research Network (SDPBRN).

Appendix 3.2: List of phrases for Google / Google Scholar search

Group 1	"Oral cancer screening guidelines" "Screening guidelines for oral cancer" "Screening for oral cancer guidelines" "Guidelines for oral cancer screening"	Group 9	"Oral cancer detection guidance" "Detecting guidance for oral cancer" "Detecting for oral cancer guidance" "Guidance for oral cancer detecting"
Group 2	"Mouth cancer screening guidelines" "Screening guidelines for mouth cancer" "Screening for mouth cancer guidelines" "Guidelines for mouth cancer screening"	Group 10	"Mouth cancer detecting guidance" "Detecting guidance for mouth cancer" "Detecting for mouth cancer guidance" "Guidance for mouth cancer Detecting"
Group 3	"head and neck cancer screening guidelines" "Screening guidelines for head and neck cancer" "Screening for head and neck cancer guidelines" "Guidelines for head and neck cancer screening"	Group 11	"Head and neck cancer detecting guidance" "Detecting guidance for head and neck cancer" "Detecting for head and neck cancer guidance" "Guidance for head and neck cancer detecting"
Group 4	"Oropharyngeal cancer screening guidelines" "Screening guidelines for Oropharyngeal cancer" "Screening for Oropharyngeal cancer guidelines" "Guidelines for Oropharyngeal cancer screening"	Group 12	"Oropharyngeal cancer detecting guidance" "Detecting guidance for Oropharyngeal cancer" "Detecting for Oropharyngeal cancer guidance" "Guidance for Oropharyngeal cancer detecting"
Group 5	"Oral cancer screening guidance" "Screening guidance for oral cancer" "Screening for oral cancer guidance" "Guidance for oral cancer screening"	Group 13	"Oral cancer early detection guidelines" "Early detection guidance for oral cancer" "Early detection for oral cancer guidance" "Guidance for oral cancer early detection"
Group 6	"Mouth cancer screening guidance" "Screening guidance for mouth cancer" "Screening for mouth cancer guidance" "Guidance for mouth cancer screening"	Group 14	"Mouth cancer early detection guidelines" "Early detection guidance for mouth cancer" "Early detection for mouth cancer guidance" "Guidance for mouth cancer early detection"
Group 7	"Head and neck cancer screening guidance" "Screening guidance for head and neck cancer" "Screening for head and neck cancer guidance" "Guidance for head and neck cancer screening"	Group 15	"Head and neck cancer early detection guidelines" "Early detection guidance for head and neck cancer" "Early detection for head and neck cancer guidance" "Guidance for head and neck cancer early detection"

Group 8	“Oropharyngeal cancer screening guidance” “Screening guidance for Oropharyngeal cancer” “Screening for Oropharyngeal cancer guidance” “Guidance for Oropharyngeal cancer screening”	Group 16	“Oropharyngeal cancer early detection guidelines” “Early detection guidance for oropharyngeal cancer” “Early detection for oropharyngeal cancer guidance” “Guidance for oropharyngeal cancer early detection”

Appendix 3.3: Sample search strategy in MEDLINE

1. ((oral or mouth or head or neck or lip* or buccal or tongue) adj5 (cancer* or neoplasm*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
2. exp cancer screening/
3. (assess* or exam* or inspect* or screen*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
4. exp "Head and Neck Neoplasms"/
5. exp Mass Screening/
6. Meta-Analysis as Topic/
7. meta analy$.tw.
8. metaanaly$.tw.
9. Meta-Analysis/
10. (systematic adj (review$1 or overview$1)).tw.
11. exp Review Literature as Topic/
12. 6 or 7 or 8 or 9 or 10 or 11
13. cochrane.ab.
14. embase.ab.
15. (psychlit or psyclit).ab.
16. (psychinfo or psycinfo).ab.
17. (cinahl or cinhal).ab.
18. science citation index.ab.
19. bids.ab.
20. cancerlit.ab.
21. 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20
22. reference list$.ab.
23. bibliograph$.ab.
24. hand-search$.ab.
25. relevant journals.ab.
26. manual search$.ab.
27. 22 or 23 or 24 or 25 or 26
28. selection criteria.ab.
29. data extraction.ab.
30. 28 or 29
31. Review/
32. 30 and 31
33. Comment/
34. Letter/
35. Editorial/
36. animal/
37. human/
38. 36 not (36 and 37)
39. 33 or 34 or 35 or 38
40. 12 or 21 or 27 or 32
41. 40 not 39
42. 2 or 3 or 5
43. 1 or 4
44. 41 and 42 and 43

Appendix 3.4: Data Extraction Form for Systematic Review (sample)

Author	Organization	Date of Publication	Number/type of study included	Interventions	Outcomes	Results	Conclusion

Appendix 3.5: Data Extraction Form for Clinical Guidelines (sample)

Author	Organization	Date of Publication	Number/type of study included	Interventions	Outcomes	Results	Conclusion

Appendix 3.6: List of included systematic reviews (n=14)

1. Gray, M., Gold, L., Burls, A., & Elley, K. (2000). The clinical effectiveness of Toluidine Blue dye as an adjunct to oral cancer screening in general dental practice. A west Midlands Development and Evaluation Service Report.
2. Truman,, B., Gooch,B.F., Sulemana, I., Gift, H.C., Horowitz, A.M., Evans, C.A., Griffin, A.O., & Carande-Kulis, V.G. (2002). Reviews of evidence on interventions to prevent dental caries, oral and pharyngeal cancers, and sports-related craniofacial injuries. American Journal of Preventive Medicine, 23 (1S), 21-36; *DARE*
3. Patton, L. L. (2003). The effectiveness of community-based visual screening and utility of adjunctive diagnostic aids in the early detection of oral cancer. *Oral Oncology*, *39*(7), 708-723. doi: 10.1016/s1368-8375(03)00083-6
4. Davenport, C.F., Elley. K.M., Fry-Smith, A., Tayllor-Weetman, C.L., & Ttaylor, .S. (2003). The effectiveness of routine dental checks: A systematic review of the evidence base. British Dental Journal, 195(2), 87-98.
5. Downer MC, Moles DR, Palmer S, Speight PM. A systematic review of test performance in screening for oral cancer and precancer. Oral Oncol. 2004 Mar;40(3): 264-73
6. Downer, M. C., Moles, D. R., Palmer, S., & Speight, P. M. (2006). A systematic review of measures of effectiveness in screening for oral cancer and precancer. *Oral Oncology, 42*(6), 551-560.
7. Patton, L. L., Epstein, J. B., & Kerr, A. R. (2008). Adjunctive techniques for oral cancer examination and lesion diagnosis: a systematic review of the literature. *J Am Dent Assoc, 139* (7), 896-905; quiz 993-894.
8. Brocklehurst, P., Kujan, O., Glenny, A. M., Oliver, R., Sloan, P., Ogden, G., & Shepherd, S. (2010). Screening programmes for the early detection and prevention of oral cancer. *Cochrane Database Syst Rev*(11), CD004150.
9. Epstein, J.B., Guneri, P., Boyacioglu, H., Abt, E. (2012). The limitation of the clinical oral examination in detecting dysplastic oral lesions and oral squamous cell carcinoma. The Journal of the American Dental Association.143(12):1332-1342).
10. Walsh T, Liu JLY, Brocklehurst P, Glenny AM, Lingen M, Kerr AR, Ogden G, Warnakulasuriya S, Scully C. Clinical assessment to screen for the detection of oral cavity cancer and potentially malignant disorders in apparently healthy adults. Cochrane Database of Systematic Reviews 2013, Issue 11. Art. No.: CD010173. DOI: 10.1002/14651858.CD010173.pub2.
11. Riley P, Worthington HV, Clarkson JE, Beirne PV. Recall intervals for oral health in primary care patients. Cochrane Database of Systematic Reviews 2013, Issue 12. Art. No.: CD004346. DOI: 10.1002/14651858.CD004346.pub4.
12. Torras, C., Gay-Escoda, C. (2015). Techniques for early diagnosis of oral squamous cell carcinoma: Systematic review.Med Oral Patol Oral Cir Bucal:1;20(3):e305-15.
13. Warnakulasuriya, S., Fennell, N., Diz, P., Seoane, J., & Rapidis, A. (2015). An appraisal of oral cancer and pre-cancer screening programmes in Europe: a systematic review. Journal of oral pathology and medicine, 44: 559-570.
14. M. Lingen, M. Tampi, O. Urquhart, et al, (2017). Adjuncts for the evaluation of potentially malignant disorders in the oral cavity: diagnostic test accuracy systematic review and meta-analysis, JADA, 148 (11)

Appendix 3.7: List of excluded systematic reviews (n=22)

Excluded systematic reviews (n=22)	Reason for exclusion
Roseinberg D, Cretin S, (1989), Use of meta-analysis to evaluate tolonium chloride in oral cancer screening. Oral Surg Med oral Pathol. 67:621-7).	Not strictly systematic review
Jullien JA, Downer MC, Evaluation of a screening test for the early detection of oral cancer and precancer (1995). Community Dental Health, 12:3-7.	Not a systematic review
Jonathan J Deeks (2001). Systematic reviews of evaluation of diagnostic and screening tests. British Medical Journal.323:157-62.	Systematic review related to diagnostic accuracy.
Moles D, Downer M, Speight P (2002). Meta analysis of measures of performance reported in oral cancer and precancer screening studies.192:340-344.	Not a systematic review
Davenport CF, Elley KM, Fry-Smith A, Taylor-Weet-man CL, Taylor RS. The effectiveness of routine dental checks: a systematic review of the evidencebase. BMJ 2003;195:87–98	Duplicate to Davenport et al (HTA paper) – to be removed.
Kujan O, Glenny AM, Duxbury AJ, Thakker N, Sloan P, Duxbury J. Screening programmes for the early detection and prevention of oral cancer. Cochrane Database of Systematic Reviews 2003, Issue 4. Art. No.: CD004150. DOI: 10.1002/14651858.CD004150.	Outdated and modified to version 2005
Kujan O, Glenny AM, Duxbury J, Thakker N, Sloan P. Evaluation of screening strategies for improving oral cancer mortality: a Cochrane systematic review. J Dent Educ. 2005;69:255-65.	Outdated and modified to version 2006
Beirne PV, Forgie A, Clarkson JE, Worthington HV. Recall intervals for oral health in primary care patients. Cochrane Database of Systematic Reviews 2005, Issue 2. Art. No.: CD004346. DOI: 10.1002/14651858.CD004346.pub2.	Outdated – updated 2008 is included in our SR list.
Kujan O, Glenny AM, Oliver R, Thakker N, Sloan P. Screening programmes for the early detection and prevention of oral cancer. Cochrane Database of Systematic Reviews 2006, Issue 3. Art. No.: CD004150. DOI: 10.1002/14651858.CD004150.pub2.	Outdated and modified to version 2010
Speight PM, Palmer S, Moles DR, Downer MC, Smith DH, Henriksson M, *et al.* The cost-effectiveness of screening for oral cancer in primary care. *Health Technol Assess* 2006;10(14).	Executive summary: to be merged with review for Davenport et al,2003.
Epstein JB, Sciubba J, Silverman S Jr, et al. Utility of toluidine blue in oral premalignant lesions and squamous cell carcinoma: continuing research and implication for clinical practice.	Not a systematic review

Excluded systematic reviews (n=22)	Reason for exclusion
Head Neck 2007;29:948-58.	
Lingen MW, Kalmar JR, Karrison T, Speight PM (2008) Critical evaluation of diagnostic aids for the detection of oral cancer. Oral Oncol 44(1):10–22	Not a systematic review
Mehanna HM, Rattay T, Smith J, McConkey CC. Treatment and follow up of dysplasia- a systematic review and meta-analysis. Head Neck. 2009;31:1600–9.	Not related to screening
Cozens, N.J.A(2009). A systematic review that evaluates one-stop neck lump clinics. Clinical Otolaryngology, 34(1)	Not related to screening
Smith J, Rattay T, McConkey C, Helliwell T, Mehanna H (2009). Biomarkers in dysplasia of the oral cavity: asystematic review. Oral Oncol 45:647–653	Not related to oral cancer screening
Brocklehurst P, Kujan O, Glenny AM, Oliver R, Sloan P, Ogden G, Shepherd S. Screening programmes for the early detection and prevention of oral cancer. Cochrane Database of Systematic Reviews 2010, Issue 11. Art. No.: CD004150. DOI: 10.1002/14651858.CD004150.pub3.	Outdated and modified to version 2010, then 2010 was modified to 2013 and it is included in our high quality systematic review.
Rethman MP, Carpenter W, Cohen EE et al (2010). Evi-dence-based clinical recommendations regarding screeningfor oral squamous cell carcinomas.J Am Dent Assoc141:509–520.	Outdated
Almuammar A, Dryden C, Burr JA. Factorsassociated with late presentation of cancer: alimited literature review.J Radiother Pract 2010;9(02):117–123	Not related to screening
Güneri P, Epstein JB, Kaya A, Veral A, Kazandı A, Boyacioglu H (2011) The utility of toluidine blue staining and brush cytology as adjuncts in clinical examination of suspicious oral mucosal lesions. Int J Oral Maxillofac Surg 40(2):155–161	Not a systematic review
Walter F, Webster A, Scott S, Emery J. The Andersen Model of Total Patient Delay: a systematic review of its application in cancer diagnosis. *J Health Serv Res Policy* 2012; 17(2): 110– 8.	Not related to oral cancer screening
Rethman MP, Carpenter W, Cohen EE, Epstein J, Evans CA, Flaitz CM, et al. Evidence-based clinical recommendations regarding screening for oral squamous cell carcinomas. Tex Dent J 2012;129: 491-507.	Add to clinical guideline list
Macey, R., Walsh, T., Brocklehurst, P., Kerr, A.R., Liu, J.L., Lingen, M.W., Ogden, G.R., Warnakulasuriya, S. and Scully, C., 2015. Diagnostic tests for oral cancer and potentially malignant disorders in patients presenting with	Systematic review related to diagnostic accuracy

Excluded systematic reviews (n=22)	Reason for exclusion
clinically evident lesions. *Cochrane Database of Systematic Reviews*, (5).	

Appendix 3.8: List of included clinical guidelines (n=20)

#	Clinical Guidelines
1	University of Glasgow Dental School.2003.Oral cancer Prevention and Detection for the primary Health Care Team.UK.2nd.Oral cancer awareness group, University of Glasgow Dental School.
2	American Cancer Society. 2003. Guidelines for the early detection of cancer. US. A cancer journal for clinician.
3	NHS. 2004. Guidance on cancer Services-Improving outcomes in head and neck cancers.UK. National Institute for Clinical Excellence.
4	National Institute for Clinical Excellence. 2004. Dental recall, recall interval between routine dental examinations, UK. National Institute for Clinical Excellence.
5	Cancer research UK. 2005. Mouth cancer referral guidelines for dentists. UK. NHS
6	Scottish Intercollegiate Guidelines Net Work.2006. Diagnostic and management of head and neck cancer. UK. Scottish Intercollegiate Guidelines Network.
7	Brouwers M, Crawford J, Elison P, Evans WK, Gagliardi A, Holmes D, et al. Organizational standards for diagnostic assessment programs. Toronto (ON): Cancer Care Ontario; 2007 Jun 15 [In review 2011 Sep]. Program in Evidence-based Care Evidence-based Series Organizational Standards for DAP IN REVIEW.
8	Agency for Health care Research and Quality. 2007. Health Partners dental group and clinics oral cancer guideline.NGC-9498. Minneapolis. US department of Health and Human Services.
9	College of Dental Surgeons of British Columbia. 2008. Guideline for the early detection of oral cancer in British Columbia. BC cancer Agency.
10	Ministry of Health .2009. Suspected cancer in primary care guidelines for investigation, referral and reducing ethnic disparities. New Zealand. New Zealand guidelines group.
11	British Dental Association.2010. Early detection and prevention of oral cancer: a management strategy for dental practice. UK.British Dental Association.
12	ENTUK (2011). Head and Neck Cancer: Multidisciplinary Management Guidelines, 4th edition. British Association of Otorhinolaryngology, Head and Neck Surgery, The Royal College of Surgeons of England.
13	Scottish Dental Clinic effectiveness Programme.2012. Oral health assessment and review dental clinic guidance. UK.1.0. Scottish Dental Clinic effectiveness Programme.
14	Australian Government. 2013. South Australian Head and Neck cancer pathway. South Australia. Department of Health and Aging, Government of South Australia.
15	National Institute of Dental and Craniofacial Research.2013.Detecting oral cancer A guide for Health Professionals.US. US department of Health and human services, National Institute of Health.
16	Memorial Sloan Kettering Cancer Center.2014.Heas and Neck Cancers. US. Memorial Sloan Kettering Cancer Center
17	U.S. Preventive Services Task Force. 2014. Screening for oral cancer: U.S. Preventive services Task Force Recommendation Statement. US. Annals of Internal Medicine.
18	Solution for Public Health.2015.Appraisal of Screening for oral cancer- a draft report for the UK National Screening Committee.UK. Solution for Public Health
19	Maryland Comprehensive cancer control plan.2016-2020. oral cancer – chapter 12. Maryland. Maryland department of health and mental hygiene.
20	American Dental Association. 2017. Evidence-based clinical practice guideline for the evaluation of potentially malignant disorders in the oral cavity: a report of the American Dental Association. US. JADA

Appendix 3.9: List of excluded clinical guidelines (n=8)

N	Clinical guidelines	Reasons
1	National Center for Chronic Disease Prevention and Health Promotion, Central for disease control and prevention.1996.Oral cancer background paper. Chapter IX: Health Promotion in oral cancer prevention and early detection. US.	Not related to OCC, working draft for CDC report.
2	British Dental Association.2000.Opportunistic oral cancer screening: A management strategy for dental practice.6.UK. British Dental Association	Management not screening
3	Centers for Disease Control and Prevention.2001.Promoting oral health: Interventions for preventing dental caries, oral and pharyngeal cancers, and sports-related craniofacial injuries.US. Epidemiology program office Centers for disease control and prevention.	recommendation statement included in guideline #19
4	National Institute for Health and Clinical Excellence.2005.Referral guidelines for suspected cancer. 27. UK. National Institute for Health and Clinical Excellence	Deal with referral not screening
5	Rethman MP, Carpenter W, Cohen EE, et al. Evidence-based clinical recommendations regarding screening for oral squamous cell carcinomas. J Am Dent Assoc 2010; 141: 509– 520.	Duplicate - published twice. 2010: Tex Dent J. 2012 May;129(5):491-507.
6	Speight, P.M. and Warnakulasuriya, S. (2010) Evaluation of Screening for Oral Cancer against National Screening Committee Criteria. UK National Screening Committee Publications. http://www.screening.nhs.uk/oralcancer	Review paper, not actual guideline document.
7	Maryland Comprehensive cancer control plan.2011-2015. oral cancer – chapter 12. Maryland. Maryland department of health and mental hygiene.	Outdated replaced with new plan 2016-2020
8	Kaiser Permanente Research Affiliates EPC. 2013. Screening for oral cancer: A targeted evidence update for the US preventive services task force.102. Agency for Health care Research and Quality.	Outdated replaced with USPSTF 2014

Appendix 3.10: Moderate Quality Systematic Review- COE

Study ID	Results and / or Conclusions
Downer et al (2004)	Prevalence OCC or OPMD = 2% - 51% Pooled weighted Sensitivity = 0.85 (95%CI 0.73, 0.92) Specificity = 0.97 (95%CI 0.93, 0.98) "A generally high level of discriminatory ability and consistency in test performance was apparent among the studies included, irrespective of their clinical heterogeneity"

Appendix 3.11: Low Quality Systematic Review- COE

Study ID	Results and / or Conclusions
Warnakulasuriya et al (2015)	Sensitivity (range) = 0.68 – 0.98 Specificity (range) = 0.71 – 0.96 "…the feasibility of screening for OPMDs by conventional oral examination has been demonstrated, supporting a strategy to adopt appropriate screening models, and further action from the European countries should be to demonstrate methods of halting their progression by tested interventions."
Carreras-Torras and Gay-Escoda (2015)	Quotes Epstein et al (2012) sensitivity data "Therefore, COE cannot reliably differentiate between benign and dysplastic lesions, and this is probably due to the fact that a number of benign conditions mimic oral malignancies."
Patton (2003)	Sensitivity (range) = 0.71 – 0.95 Specificity (range) = 0.64 – 0.99 "Routine oral visual examination can result in earlier detection of oral cancer, allowing interventions that contribute to reduced morbidity and/or improved survival. Mainly important is the identification and motivation of people in high-risk groups (tobacco and alcohol users) who do not attend the health care regularly for targeted screening or clinical examination tobacco cessation interventions."
Walsh et al (2013)	"... even though the evidence of accuracy is not consistently strong, there is some evidence ... that implementing COE as a component of a population screening programme can reduce mortality and produce stage-shift in a high-risk population." "General dental practitioners and dental care professionals should remain vigilant for signs of OPMD and oral cancer whilst performing routine oral examinations in practice."
Brocklehurst et al (2013)	"There is evidence that a visual examination as part of a population-based screening programme reduces the mortality rate of oral cancer in high-risk individuals." "However, the evidence is limited to one study, which has a high risk of bias and did not account for the effect of cluster randomisation in the analysis." "... good evidence that opportunistic screening of high-risk groups is cost-effective" ... "However, these results also need to be read in context of the relative prevalence of the condition." "The results suggest that there is insufficient evidence to recommend a whole population screening programme for oral cancer. However, the results from the Kerala study suggest that a targeted population approach could reduce the mortality rate and produce a stage shift, but the risk of bias in the included study means that further well-designed randomised controlled trials are necessary to establish the validity of this relationship." "In the meantime, opportunistic visual screening by appropriately trained dentists and oral health practitioners is recommended for all patients and particularly for those who use tobacco, alcohol or both. Systematic examination of the oral cavity by front-line health workers should remain an integral part of their routine for routine recall appointments."

Appendix 3.12: Moderate Quality Clinical Guidelines - COE

CG –ID	Year	Recommendations	Evidence Rating
AHRQ	2007	"Visual examination of the oral soft tissues, extraoral head and neck tissues and palpation of the head and neck lymph nodes is considered the standard of care as part of a complete dental examination."	"Major Recommendation". Based on no quality of evidence rating, with no strength of recommendation assigned.
BDA	2010	"Head and neck and oral soft tissue examination should be carried out …"	"Key Point" Based on no quality of evidence rating, with no strength of recommendation assigned.
SDCEP	2012	"Conduct a comprehensive extra-oral examination of the patient's head and neck, including: skin (including swellings) facial bones lymph nodes temporomandibular joint Conduct comprehensive intra-oral examination oral mucosal tissue."	"Actions for the dental team" Based on no quality of evidence rating, with no strength of recommendation assigned
SCCN	2013	"… dental and medical examinations with appropriate health questionnaires (such as skin, voice, oral symptoms, swallowing and behavioural assessments for risk factors)."	Based on no quality of evidence rating, with no strength of recommendation assigned
UKSPH	2015	"… We agree with the conclusion of the Cochrane review by Walsh et al (2013) that there is insufficient evidence to determine the screening test accuracy of conventional oral examination, vital rinsing, light-based detection, biomarkers or mouth self examination, used singly or in combination. The only relevant study (Ibrahim et al 2014) published after the Cochrane review claimed 100% sensitivity for conventional oral examination with or without light-based detection and vital rinsing, but since the study design could not reliably ascertain cases of oral cancer that were missed by screening (i.e they only offered biopsy to people with suspicious lesions and did not report any follow-up".	Based on insufficient evidence from Walsh et al (2013).
MSCCC	2016	"Increase the proportion of adults age 18 and older who have had an oral cancer exam in the past year."	Screening Target – Based on US guidelines.

Appendix 3.13: Low Quality Clinical Guidelines - COE

CG – ID	Year	Recommendations	Evidence Rating
GU-GDS	2003	"… examination of the oral mucosa is important in the early detection of oral cancer or potentially malignant lesions." "… conduct a comprehensive examination for oral cancer."	Based on no quality of evidence rating, with no strength of recommendation assigned.
NIDCR	2013	"… dental check-up is an excellent opportunity for a head and neck examination."	Based on no quality of evidence rating, with no strength of recommendation assigned.
MSKCC	2014	"… primary care physicians … physical examination of the head and neck and oropharynx (the middle section of the throat that includes the soft palate, the base of the tongue, and the tonsils)." "… routine dental evaluation that includes examination of the neck and inspection of the oropharynx and the mouth."	"Our doctors recommend" Based on no quality of evidence rating, with no strength of recommendation assigned.

Appendix 3.14: Low Quality Systematic Review- Target Population

Study ID	Results and / or Conclusions
Warnakulasuriya et al, (2015)	"It is interesting to note that several models of screening have been adapted in these European studies. Screening of high-risk groups rather than the whole population has been addressed by few authors." "Target population: Constraints: There is no evidence of benefits from population-based screening in Europe. Recommendation: On the basis of the balance of benefits and harms, opportunistic screening in dental practices or screening selected high-risk population groups may be considered for future studies." "The feasibility of conducting screening studies in dental practices has however been criticised... in that the approach does not attract high-risk individuals, which the authors refer to as the 'Inverse Screening Law.'"
Patton (2004)	"Oral cancer screening programmes in low-incidence areas of the world might be more cost effective if they target high-risk populations and obtain good compliance of the selected individuals with the screening process. "Low compliance with organized oral cancer community screening programmes and low general population prevalence of oral premalignant and malignant lesions suggest population-based oral cancer screening in many regions of the world may not result in reduced morbidity and mortality associated with oral cancer and hence may not be cost-effective." "However, given the substantial morbidity and mortality that results when oral cancer is diagnosed in advanced stages, adults above the age of 40 years should undergo regular oral cancer examinations as part of medical and dental health check-ups. Routine oral visual examinations can result in earlier detection of oral cancer, allowing interventions that contribute to reduced morbidity and/or improved survival. Particularly important is the identification and motivation of people in high-risk groups, such as tobacco and alcohol users who do not regularly access health care, for targeted screening or clinical examination and tobacco cessation interventions."
Downer et al. (2006)	"Overall, this review confirms that there are insufficient available data to make a determination as to the effectiveness of oral cancer screening programmes at the present time. However, since the review was completed evidence has emerged that screening high risk individuals, in developing countries at least, could be an effective prevention strategy."

Appendix 3.15: Moderate Quality Clinical Guidelines- Target Population

CG –ID	Recommendations	Evidence Rating
CDSBC (2008)	"It is the expectation that a head, neck and oral soft tissue examination is completed on all patients at the time of the new patient examination and at general dental recall [appointment]."	Based on no quality of evidence rating, with no strength of recommendation assigned.
BDA (2010)	" The UK Working Group on Screening for Oral Cancer and Precancer recommended "opportunistic screening" as the most suitable model for the UK population, based on the availability of dental manpower and the fact that most people return to a dentist annually for a mouth examination." "NSC-UK does not recommend population screening for oral cancer, opportunistic case detection in routine practice is recommended by professional organizations"	Based on the National Screening Committee (NSC- UK) recommendation (2003), but no strength of recommendation assigned
MCCCP (2011)	"Incorporating routine oral cancer examinations ... into the daily practice of health care practitioners can increase the likelihood of earlier detection of oral cancer. However, there is no evidence that such early detection can decrease oral cancer mortality, nevertheless, routine examinations for early detection of oral cancer should still be recommended." "For those at highest rIsk for oral cancer, access to the health care system is limited both in the US and in Maryland. Access is critical in order to receive timely and appropriate oral cancer examinations. It is well established that those populations with the highest oral cancer mortality rates experience the poorest access to the overall health care." "Increase oral cancer screenings among adults by providing access to both primary care providers and oral health providers for low-income and underserved adult populations in Maryland by supporting community health centers, mobile screening services, seeking new funding sources (public and/or private), and advocating for policy changes and funding at the local, state, and federal levels."	Based on no quality of evidence rating, with no strength of recommendation assigned.
SDCEP (2012)	"Carry our assessment of the head and neck of each patient" "Conduct an examination of each patient's oral mucosal tissue in a systematic manner …"	Based on no quality of evidence rating, with no strength of recommendation assigned.
UKSPH (2015)	"The distribution of test values in the target population should be known and a suitable cut-off level defined and agreed: Criteria not met"	Based on no quality of evidence rating, with no strength of recommendation assigned

Appendix 3.16: Low Quality Clinical Guidelines- Target Population

CG -ID	Recommendations	Evidence Rating
ACS (2003)	" On the occasion of a periodic health examination, the cancer-related check-up should include examination for cancers of the ... oral cavity ... as well as health counselling about tobacco, ...risk factors" "…the ACS now recommends that the cancer- related check-up occur on the occasion of a general, periodic health examination, rather than as a stand-alone exam done at a specific interval based on an individual's age". "Recommendations for the early detection of cancer in Average-Risk, asymptomatic people is men and women age 20+.".	Based on no quality of evidence rating, with no strength of recommendation assigned.
CRUK (2005)	" Patients should be examined for potential malignancy at every dental examination." "The level of suspicious should be higher if the patient is smoker or heavy alcohol drinker, chews betel nut (Areca nut) or tobacco, or is over 40 years."	Based on no quality of evidence rating, with no strength of recommendation assigned.
NIDCR (2013)	"A regular dental check-up is an excellent opportunity for a head and neck examination" "Clinicians should be particularly vigilant in checking those who use tobacco or excessive amounts of alcohol."	Based on no quality of evidence rating, with no strength of recommendation assigned.
MSKCC (2014)	"routine dental evaluation "Recommend ... physical examination of the head, neck, and oropharynx by your primary care physician." "Recommend ... routine dental evaluation that includes examination of the neck and inspection of oropharynx and the mouth".	"Our doctors recommend" Based on no quality of evidence rating, with no strength of recommendation assigned.

Appendix 3.17: Moderate Quality Systematic Review- Frequency of COE

Study ID	Results and / or Conclusions
Davenport et al (2003)	"There is little existing evidence to support or refute the practice of encouraging 6-monthly dental check-ups." "Oral cancer Outcomes... ... no association between dental check frequencies ≥ 12/12 and < 12/12 and a diagnosis of oral cancer and precancer" [one cross-sectional study]. "... decreasing dental check-ups frequencies (>12/12 only and for intervals decreasing by ≥ 12/12) may results in a significantly increased tumor size and more advanced stage at diagnosis" [one retrospective case-series study].

Appendix 3.18: Moderate Quality Clinical Guidelines – Frequency of COE

CG -ID	Year	Recommendations	Evidence Rating
SAHNCP	2013	".. Promotion of 6 -12 monthly dental and medical examinations with appropriate health questionnaires (such as skin, voice, oral symptoms, swallowing, and behavioural assessments for risk factors".	Based on no quality of evidence rating, with no strength of recommendation assigned.
SDCEP	2012	"… it is important that on registering with a dental practice, each patient receives a baseline comprehensive Oral Health Assessment (OHA). For adults, this is repeated after 24 months". "In addition, during these time periods Focused Oral Health Review (FOHRs) can be carried out. Both the number of FOHRs and the intervals between them will vary depending on the patient's risk of future oral disease." " NICE recommends the following shortest and longest intervals between one assessment and the next assessment: • The shortest interval for all patients is 3 months. • The longest interval for patients younger than 18 years is 12 months. • The longest interval for patients aged 18 years and older is 24 months. To operationalise this approach, it is recommended that after the first Oral Health Assessment, if it is considered necessary, the patient receives Focussed Oral Health Reviews (FOHRs) at variable risk-based intervals. At a FOHR, primarily those elements previously rated as high or medium risk are reassessed... Subsequently, it is recommended that patients receive a full Oral Health Assessment every 24 months after their last full OHA for adults and 12 months after their last full OHA for children. This ensures that each patient has a regular comprehensive assessment and reflects the maximum intervals recommended by NICE.	Based on no quality of evidence rating, with no strength of recommendation assigned.
BDA	2010	"Since the objectives is opportunistic case finding rather than invitational screening, there is no precise answer to a question about the desirable intervals between mouth examinations."	Based on no quality of evidence rating, with no strength of recommendation assigned.

		"Every patient needs tailored advice, however, and your practice routine should follow the NICE guidance on recall intervals. This takes into account all aspects of oral heath, including age and risk factors".	
CDSBC	2008	"On the basis of present evidence and the potential for benefit, it is recommended that systematic oral cancer screening be offered... At present, our consensus recommendation is to offer this annually to all individuals from age 40".	Based on no quality of evidence rating, with no strength of recommendation assigned.
AHRQ	2007	"A complete inspection of the oral and oropharyngeal soft tissue and head and neck lymph nodes should be conducted at each dental hygiene exam appointment. An individual determined to be at risk for oral cancer may require a more frequent recall intervals than caries and periodontal risks would dictate."	Based on no quality of evidence rating, with no strength of recommendation assigned.

Appendix 3.19: Low Quality Clinical Guidelines – Frequency of COE

CG -ID	Year	Recommendations	Evidence Rating
MSCC	2014	"... all individuals visit their primary care physician for a yearly physical examination of the head and neck and oropharynx" "... also recommend a yearly routine dental evaluation that includes examination of the neck and inspection of the oropharynx and the mouth".	Based on no quality of evidence rating, with no strength of recommendation assigned.

Appendix 3.20: Moderate Quality Systematic Review- Adjunct Tools

Study ID	Results and / or Conclusions
Patton et al (2008)	"There is evidence that TB [Toluidine Blue] is effective as a diagnostic adjunct for use in high risk populations and suspicious mucosal lesions. OralCDx [cytopathology brush biopsy] is useful in assessment of dysplastic changes in clinically suspicious mucosal lesions; however, there are insufficient data meeting the inclusion criteria to assess usefulness in innocuous mucosal lesions. Overall, there is insufficient evidence to support or refute the use of visually based examination adjuncts." "..the sensitivities of TB as a diagnostic adjunct varied from 38 to 98 percent (median, 85 percent) and specificities varied from 9 to 93 percent (median, 67 percent). The PPVs ranged from 33 to 93 percent (median, 85 percent) and the NPVs from 22 to 92 percent (median, 83 percent)." "Most of the studies [with the better outcomes] either were conducted in referral specialty clinics ["oral mucosal disease clinics"] or involved surveillance or higher-risk populations … Therefore, the underlying population prevalence of OPML [oral potentially malignant lesions] in these studies was higher than that expected in a general dental practice with a low-risk population." "…the results… of our systematic review support a recommendation for the use of TB as a surveillance or diagnostic adjunct in populations at higher risk." "Given lack of data on the effectiveness of adjunctive cancer detection techniques in general dental practice settings…"
Downer et al (2004)	"…there were no known studies or clinical trials of this agent [toluidine blue] in progress as a screening test for oral cancer in a general practice setting." "No reports were found of the use of toluidine blue dye as an aid in population screening of apparently healthy individuals for oral cancer and precancer…its use in screening in primary care would not be beneficial and could not be recommended."
Gray et al (2000)	"No published studies have evaluated the use of toluidine blue dye in the general population. The one study in primary care had 140 patients and did not have the power to demonstrate any effect. There is no evidence that toluidine blue is effective in screening for oral cancer in primary care." "Case series reports of the use of toluidine blue in secondary care show variable results in terms of the sensitivity and specificity of the test….the quality of these included studies is poor." "[In the 14 included studies]…Reported sensitivity varies from 1.0 to 0.4. Since it is not proposed that toluidine blue screening be used to exclude the requirement to biopsy a visible lesion, the sensitivity of the test is not relevant (otherwise a negative result in a highly sensitive test could have been used exclude the need for biopsy). The reported specificity of toluidine blue varies from 0.31 to 0.92." "The 14 studies in secondary care were all of people at high risk of oral cancer and all but one of the studies concerned people referred to secondary care with oral lesions. Thus, the results of the included studies relate to the test characteristics of toluidine blue as a screening test for oral cancer in people with detected oral lesions and are not generalisable to primary care." "Economic Analysis: The cost per case detected would be £861,700…. it would cost £2,872,333/person cured. This is probably an underestimate of cost as most of the assumptions… are very optimistic and the calculation does not include treatment costs. Moreover there would be 45,000 people who were made anxious per person cured." "Currently there is no evidence to suggest that toluidine blue is a cost-effective method of picking up oral cancers in a primary care setting. Given the large number of people that will have false positive rates for a first positive test and even a double positive test, the harm of using it in terms of anxiety could well outweigh the benefits in terms of additional cancers detected."

Appendix 3.21: Low Quality Systematic Review- Adjunct Tools

Study ID	Results and / or Conclusions
Carreras-Torras & Gay Escoda (2015)	"The best diagnostic techniques is that which we have sufficient experience and training. Definitely tissue biopsy and histopathological examination should remain the gold standard for oral cancer diagnose. In this systematic review it has not been found sufficient [sic] scientific evidence on the majority of proposed techniques for early diagnosis of OSCC and OPMD." The clinical application of toluidine blue has been shown to be selective staining of premalignant and malignant lesions… has a high sensitivity, but a low specificity due to the false positive that generates…. So, is recommended as an adjunct to the clinical examination of oral mucosal lesions, specifically in high-risk patients by expert providers,…"
Patton (2003)	"Toluidine blue has not been routinely used by physicians or dentists to screen either general or high-risk populations, and no community-based screening programmes could be identified that used this vital dye to aid visual exam." "Toluidine blue …. sensitivities ranging from 97.8 to 93.5%, and specificities ranging from 92.9 to 73.3%, it was concluded that if toluidine blue is used to screen high-risk populations, the likelihood of a false negative finding is extremely low, whereas false positive results will be relatively numerous. However, given the high sensitivity of the test, the absolute number of false positive tests will be small… More recent studies…have demonstrated equally high sensitivities, but specificities as low as 45%, leading to a larger number of false positive results, generally caused by retention of stain in areas of inflammation or trauma. Tests with high false positive rates may be most beneficial when used in appropriately selected high-risk populations, thus making them less amenable to use as diagnostic aids in community-based screenings" "While the evidence is fair to support use of toluidine blue as an aid in diagnosis of oral cancer, there is insufficient evidence to determine whether the use of this or other adjunctive techniques will increase the detection or oral malignancies in community screening programmes." "Adjunctive oral cancer screening aids, such as toluidine blue vital dye, may be effective in certain clinical settings. Additional studies are needed to evaluate the effectiveness of the oral cyto-brush and toluidine blue vital dye as aids to oral cancer screening in high risk community settings".

Appendix 3.22: Moderate Quality Clinical Guidelines – Adjunct tools

CG -ID	Recommendations	Evidence Rating
SPH (2015)	"Has a reliable test suitable for use in primary care been identified? This may be an alternative or an adjunct to the visual examination." "One of the questions for this current review is 'has a reliable test suitable for use in primary care been identified? This may be an alternative or an adjunct to the visual examination.' Potential adjunct tests include: • Vital rinsing or staining (Toluidine blue, Tolonium chloride) • Light-based detection (e.g. ViziLite and ViziLite Plus, Microlux/DL, VELscope, Orascoptic DK, Identafi 3000) • Mouth self-examination • Blood and saliva analysis." "Criteria not met".	Based on no quality of evidence rating, with no strength of recommendation assigned.
BDA (2010)	"There is also the option, now, of using several chairside adjuncts to assist in oral mucosal screening, but the clinical decision (to refer or to monitor) should not be entirely based on these tools for the following reasons: 1. They are not sufficiently tested in primary care, so the evidence for their effectiveness in primary care is lacking. 2. Though the sensitivity is high (they can detect most lesions), the specificity remains low (they can also detect many benign lesions), leading to high false positive rates and unnecessary referrals. For most patients, a soft tissue examination without any use of adjuncts will be completely adequate. And you might, very occasionally, see a lesion that so obviously needs to be referred to a specialist that any additional investigation in practice would not be needed. But for high risk patients without obvious lesions, the accuracy of an examination can be increased and there is	

	also a possible benefit in the way the use of an adjunct raises patient awareness of a risk." "Any diagnostic test for identifying a malignancy should not be used as a substitute for a thorough clinical examination." "Adjunct tests can improve visibility and detection, but must not be used as a sole method for detecting lesions."	
CDSBC (2008)	"Adjunctive screening tools may be of added value and could be considered in conjunction with annual oral cancer screening examination or at the time of identification of any suspicious lesion" "Techniques currently used by the BC Oral Cancer Prevention Program affiliated clinics include toluidine blue staining and direct fluorescence visualization… Although these techniques are not diagnostic alone, they may enhance lesion characteristics, identify satellite lesion sites and assist in biopsy site selection. These techniques are complementary to and not a replacement for the comprehensive history and conventional visual and manual head, neck and oral examination. Good clinical judgment remains indicated in all circumstances." "Toluidine blue Staining: The research was conducted at the BC Cancer Agency has shown that biopsy-proven oral malignant lesions that stain positively are six times more likely to become oral cancers than those that do not. The finding supports a role for this vital stain in identification of high-risk oral lesions."	Based on no quality of evidence rating, with no strength of recommendation assigned.
AHRQ (2007)	"Adjunctive toluidine blue dye to enhance the screening examination did not significantly improve detection of lesions nor reduce oral cancer incidence compared with a placebo-dye screening examination. No study evaluating other adjuncts (chemiluminescent lighting, auto fluorescent lighting, or brush cytopathology) met our inclusion criteria."	Based on no quality of evidence rating, with no strength of recommendation assigned.

Appendix 3.23: Low Quality Clinical Guidelines – Adjunct tools

CG -ID	Year	Recommendations	Evidence Rating
GU-GDS	2003	"Toluidine blue staining has gained support in some centres as a screening test for potentially malignant and malignant lesions of the oral mucosa. Whilst this technique may have some limited application in specialist centres, screening in the primary care setting should be focused upon detection of mucosal abnormalities by direct visualisation during a thorough examination of the oral tissues."	Based on no quality of evidence rating, with no strength of recommendation assigned.

Appendix 4.1: MVLS Ethical Approval (OHCPs)

University of Glasgow | College of Medical, Veterinary & Life Sciences

16th June 2016

Dear Dr Ross

MVLS College Ethics Committee

Project Title: Oral cancer risk assessment, examination and prevention: cross national pre-pilot interviews to explore implementation of best practice and clinical guidelines

Project No: 200150168

The College Ethics Committee has reviewed your application and has agreed that there is no objection on ethical grounds to the proposed study. It is happy therefore to approve the project, subject to the following conditions:

- Project end date: 31 October 2016
- The data should be held securely for a period of ten years after the completion of the research project, or for longer if specified by the research funder or sponsor, in accordance with the University's Code of Good Practice in Research: (http://www.gla.ac.uk/media/media_227599_en.pdf)
- The research should be carried out only on the sites, and/or with the groups defined in the application.
- Any proposed changes in the protocol should be submitted for reassessment, except when it is necessary to change the protocol to eliminate hazard to the subjects or where the change involves only the administrative aspects of the project. The Ethics Committee should be informed of any such changes.
- You should submit a short end of study report to the Ethics Committee within 3 months of completion.

Yours sincerely

Dorothy McKeegan

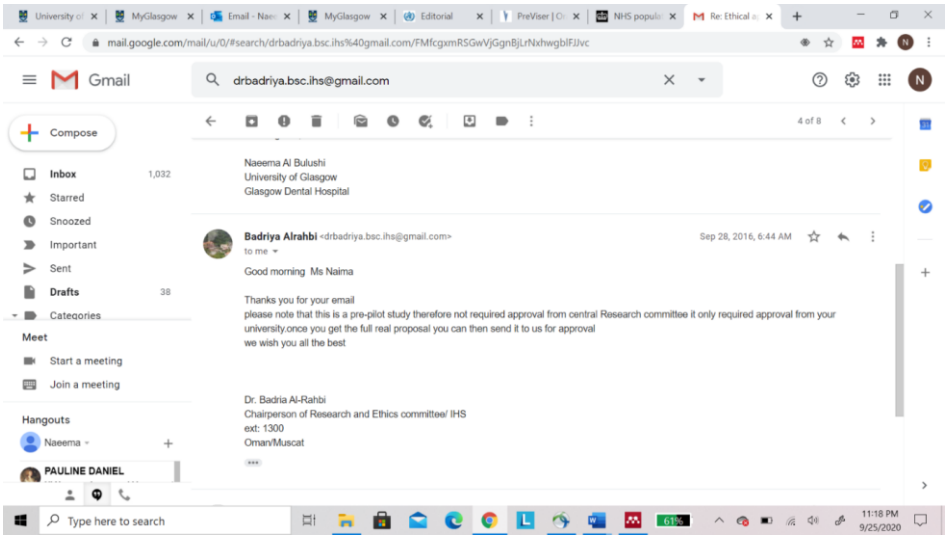
Dr Dorothy McKeegan
College Ethics Officer

Dr Dorothy McKeegan

Senior Lecturer

R303 Level 3
Institute of Biodiversity Animal Health and Comparative Medicine
Jarrett Building
Glasgow G61 1QH Tel: 0141 330 5712
E-mail. Dorothy.McKeegan@glasgow.ac.uk

Appendix 4.2: MOH Ethical Approval (OHCPs)



From: **Badriya Alrahbi** <drbadriya.bsc.ihs@gmail.com>
Date: Wed, Sep 28, 2016 at 6:44 AM
Subject: Re: Ethical approval for the 2nd project
To: Naeema Al Bulushi <nmalbulushi@gmail.com>

Good morning Ms Naima

Thanks you for your email
please note that this is a pre-pilot study therefore not required approval from central Research committee it only required approval from your university.once you get the full real proposal you can then send it to us for approval
we wish you all the best

Dr. Badria Al-Rahbi
Chairperson of Research and Ethics committee/ IHS
ext: 1300
Oman/Muscat

Appendix 4.3: NHS Approval for OHCPs

NHS
Greater Glasgow and Clyde

WoSRES
West of Scotland Research Ethics Service

Ms Sweta Mathur
PhD Student
Glasgow Dental Hospital & School
University of Glasgow

West of Scotland Research Ethics Service
Ground Floor – The Tennent Institute
Western Infirmary
38 Church Street
Glasgow G11 6NT

Date	20th March 2015
Our Ref	WoS ASD 984
Direct line	0141 211 2126
Fax	0141 211 1847
E-mail	Judith.Godden@ggc.scot.nhs.uk

Dear Ms Mathur

Full title of project: Oral Cancer Risk Assessment and Prevention: Best Practice and Implementation of Clinical Guidelines

You have sought advice from the West of Scotland Research Ethics Service Office on the above project. This has been considered by the Scientific Officer and you are advised that based on the submitted documentation (email correspondence 11th February 2015) it does not need NHS ethical review under the terms of the Governance Arrangements for Research Ethics Committees (A Harmonised Edition). This advice is based on the following.

- The participants are neither patients nor relatives or carers of patients (recruited for this reason) and therefore the study does not fall within the scope of the NHS Research Ethics Committee system (GAfREC 2011)

Note that this advice is issued on behalf of the West of Scotland Research Ethics Service and does **not** constitute a favourable opinion from a REC. It is intended to satisfy journal editors and conference organisers and others who may require evidence of consideration of the need for ethical review by an NHS REC prior to publication or presentation of your results.

This project may require NHS Management Approval and you should check with the appropriate Health Board R&D Department before commencing the study.

Kind regards

Dr Judith Godden, WoSRES Scientific Officer/Manager

Appendix 4.4: Participants Information Sheet (OHCPs)

University of Glasgow | College of Medical, Veterinary & Life Sciences

INFORMATION ABOUT THE RESEARCH

"Oral cancer risk assessment and prevention: cross national pre-pilot interviews to explore implementation of best practice and clinical guidelines"

Introduction

You are being invited to take part in a research study. Before you decide whether to take part in the study, it is important that you understand why the research is being done and what it will involve for you. Please take some time to read the following information carefully. Feel free to discuss the study with others before you decide. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

The study is a qualitative study, involving individual interview (one-to-one) to explore the views of dental teams in Scotland and Sultanate of Oman on oral cancer examination and prevention guidance. We want to find out the barriers and facilitators to oral cancer risk assessment, oral examination, preventive advice and referral in dental practice.

Why have I been chosen?

You are being asked to take part in the study because you are working in General Dental Practice and can inform us as to the feasibility of translation research evidence and guidelines to everyday working environments.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part, please remember that you are free to withdraw at any time and without giving a reason.

What will happen to me if I take part?

We will invite you to participate in a 30-45 minute face-to-face interview. Questions will focus on the current barriers and facilitators to oral cancer risk assessment, examination, patient recall, advice-giving and referral in dental practice. We would also like to explore which aspect of best practice for oral cancer risk assessment, examination and prevention are transferrable to dental practice to improve outcomes for patients.

We will make sure that you are happy with being tape-recorded beforehand.

What do I have to do?

If you are happy to take part, we will contact you to arrange a mutually convenient time for the interview. If you do not want to take part, we will not contact you again.

What are the possible disadvantages and risks of taking part?

There are no identified risks and it is very unlikely that you will come to any harm as a result of taking part in the study. However, if you feel uncomfortable or do not wish to continue at any time, you can leave the discussion without giving any reason.

What are the possible benefits of taking part?

We hope the information that will be collected during this study will be useful to support implementation and sustained use of oral cancer guidance in risk assessment, examination, prevention and referral for the benefit of the public.

Each face-to-face interview participant will receive CPD allowance (CPDA) from NES in direct return for participation in the study. **(Scotland Only)**

Will my taking part in this study be kept confidential?

Your information will be kept strictly confidential and anonymous. You will only be identified by an ID number, and any information about you will have your name removed so that you cannot be recognized from it. The anonymized interview notes and your records will be held securely for at least 10 years at the University of Glasgow (in accordance with Medical Research Council best research practice guidelines). We will then destroy them.

What will happen to the results of the research study?

The results will be used to write a PhD thesis, and will be made available as scientific papers in journals and presentations at seminars and/or conferences. We can also send you a short summary of the findings if you wish.

Who is organising and funding the research?

The study is being conducted by the Glasgow Dental Hospital and School at the University of Glasgow. The study is funded by NHS Education for Scotland, Glasgow Dental Educational Trust, and Ministry of Health - Sultanate of Oman.

Who has reviewed the study?

The project has been reviewed by the College of Medicine, Veterinary and Life Sciences ethics committee, NHS West of Scotland Research Ethics Service (WoSRES) and NHS R&D Management committee. A study proposal has also been submitted to the Glasgow Dental Hospital and School Research Management Committee.

Contact for Further Information:

Please contact Dr Sweta Mathur at s.mathur.1@research.gla.ac.uk or +44 777 839 1940;

Mrs Naeema Al Bulushi at n.al-bulushi.1@research.gla.ac.uk or +44 749 451 0033; 00968 92303333 (Oman)

If you have any concerns about any aspect of this study, please contact Dr Alastair Ross at alastair.ross@gla.ac.uk or +44 141 211 9811

Thank you for taking the time to read this information.

Appendix 4.5: Consent Form (OHCPs)

University of Glasgow College of Medical, Veterinary & Life Sciences

Project Number: 69121

CONSENT FORM

Title of Project:
Oral cancer risk assessment, examination and prevention: cross national pre-pilot interviews to explore implementation of best practice and clinical guidelines

Name of Researcher(s):
Dr Sweta Mathur; Mrs Naeema Al Bulushi; Dr Alastair Ross; Prof David Conway; Prof Lorna Macpherson; Prof John Gibson

Please initial box

I confirm that I have read and understand the information sheet dated May 2016 (version v1.4.1) for the above study and have had the opportunity to ask questions.	☐
I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my legal rights being affected.	☐
I give my permission for the interview that I take part in to be tape-recorded.	☐
I agree to take part in the above study.	☐

Name of subject	Date	Signature
Name of Person taking consent (if different from researcher)	Date	Signature
Researcher	Date	Signature

(1 copy for subject; 1 copy for researcher)

Appendix 4.6: Interview Topic Guide (OHCPs)

University of Glasgow | College of Medical, Veterinary & Life Sciences

Interview Topic Guide

[**For oral cancer feasibility interviews in Scotland and Sultanate of Oman; to be used in conjunction with slides/ display outlining the suggested stages of the pilot study]**

Title of Project:

Oral cancer risk assessment, examination and prevention: cross national pre-pilot interviews to explore implementation of best practice and clinical guidelines

1. INTRODUCTION

a) Introduce self and study background (i.e. systematic reviews/ evidence synthesis/ Scotland and Oman/ INHANCE/ pilot trial)

b) Have you read the information sheet and consent form? Do you have any questions regarding this?

c) I will audio-record the discussion, and the recordings will be kept for 10 years after the project finishes, but everything you say will be in strictest confidence.

d) Aim of these interviews: I would like to know about the current barriers and facilitators to oral cancer risk assessment, examination, recall interval, advice-giving and referral in dental practice. I would also like to explore which aspect of best practice for oral cancer risk assessment, examination and prevention are transferrable to dental practice to improve outcomes for patients.

e) I would also like to know your views on current practice and any suggestions to help us guide our development of an oral cancer prevention and early detection intervention and trial.

2. GENERAL INFO

a) **What is your current role/title?**
b) **How long have you been practicing?**
c) **What if any is your background relating to oral cancer?**
    i. Any training? CPD? specialty etc.?

3. CURRENT PRACTICE

a) **What risks of oral cancer do you know about?**
    i. Smoking/ alcohol
    ii. Age/gender/socioeconomic status/education/family history
    iii. Do you ever discuss oral cancer risks with your patients? Is this as a norm if they have risk factors? Or if patients bring it up?
    iv. Do you target people based on risk?
b) **Examination, prevention and recall: Do you take these risks into account?**
    i. How do you find out about these things?
        1. When / how do you take social history?
    ii. Do you use any assessment/screening tools?
c) **Do you carry out oral soft tissue examinations / and extra-oral examinations?**
    i. How? Do you follow any guidelines?
    ii. Do you use any adjunct tools?
    iii. Why do you carry these out? on whom? When? How often?
d) **How many patients have you seen with oral cancer / suspicious lesions etc.?**
    i. What happened next?
    ii. What about referral, follow up, recall?
e) **Do you ever give people advice on smoking?**
    i. How? Who? When?
f) **Do you ever give people advice on drinking?**
    i. How? Who? When?
g) **Have you ever referred anyone on to another service for their smoking/ drinking?**
    i. How? What? [cessation /counselling service etc.]
    ii. What did that involve? or signpost – i.e. provide smoking quit line telephone number?
    iii. If not- why?
h) **Is there anything you think is missing/not working in your practice on oral cancer?**

i. What?
ii. What might improve things?

4. **RISK PROFILING/ASSESMENT:** [INTRODUCE THE INHANCE GRAPHIC]

   a) Are you aware of risk assessment tools for breast cancer, cardiovascular diseases, etc.?

   b) What are your general views on this type of tool?

   c) Would it help to have a tool for oral cancer that profiled/ quantified risk using this type of information? (red, amber or green)

   d) How would it work best in practice?
      i. Where? When? Who?
      ii. 2 Ways of using this tool:
         1. Self-completion in waiting room- when patient come to you
            risk already calculated for your (save your time)?
         2. go over with dental professional- as part of oral health assessment (help to break ice and tailor advice)?
      iii. Online tool/ as an app/ paper questionnaire?

   e) Would you/ could you use this as a decision tool?
      i. To guide Oral exams? Preventive strategies? Recall? Referral?
      ii. How would it help? Or What would the difficulties be?

   f) Would this tool help to introduce patient with term 'oral cancer risk'?

   g) What about colleagues/ others that you know about/ work with?
      i. What would they think about this type of profiling?

5. **EXAMINATION [SHOW BRIEF EVIDENCE SUMMARY FROM NAEEMA'S REVIEW]**

a) **What are your general views on a comprehensive intra and extra oral examination?**
    i. Who should get it, when, how often?
    ii. Including specifically pulling the tongue out with and examining posterior lateral border and under surface..
b) **Should it be <u>targeted to a risk profile</u> e.g. charting/ recall interval etc.?**
c) **How should it be explained/ introduced?**
    i. Would it be good to tie it to a risk profile? or described as an "oral cancer check"?
        1. How would you feel about this? How do you think your patients would feel about this?
    ii. How does this soft tissue exam fit within a more general oral health assessment (including medical history/ dental charting/ BPE/ periodontal chart)?

6. ADVICE/ BRIEF INTERVENTION [GIVE BRIEF EVIDENCE SUMMARY FROM SWETA'S REVIEW]

a) **Would you be comfortable giving brief (up to 5 min. at least) advice/counselling on Smoking, <u>again tied to the risk profiling?</u>**
    i. Why? What would help?
    ii. When would this be possible/ useful, if at all?
b) **Would you be comfortable giving brief (up to 5 min. at least) advice/counselling on Alcohol, <u>again tied to the risk profiling?</u>**
    i. Why? What would help?
    ii. When would this be possible/ useful, if at all?
c) **Would you attend training to learn how to counsel/ advise patients on their behaviours?**
    i. Why/ why not? What about e-learning/ CPD type activity?
    ii. How much training would you think appropriate: 1 session (half a day) or 2 sessions (1 day)?
d) **Who is the best member of the dental team to give such advice?**
    i. Dentist, Nurse, hygienist/therapist; why?
e) **What are the benefits/ drawbacks of advice/ counselling following from INHANCE risk profile?**
    i. Having previously completed the risk tool – do you think the "ice will have been broken"?
f) **What should go alongside brief counselling?**
    i. Self-help materials, follow up, goal setting

7. REFERRAL

a) Would you be comfortable referring patients to services <u>based on risk profiles?</u>

i. more intensive counselling, NRT/ pharmacological support, group activities

b) Would you/ could you follow patients up to see if it worked?

8. OTHER

a) Is there anything about oral cancer early detection/ advice/ prevention we haven't covered?

b) Anything else at all you wish to say?

Thank you very much. I appreciate the time you took for this interview.

Appendix 5.1: Topic Guide

"Oral (mouth) cancer risk assessment, examination and prevention: patients' views and experiences to develop an intervention to implement best practice and clinical guidelines in general dental practices in Scotland and the Sultanate of Oman"

9. <u>INTRODUCTION</u> (introduce self)

- Have you read the information sheet and consent form? Do you have any questions regarding this?
- I would like to know your views and experiences of previous and current dental practice visits in relation to oral/mouth examination, advice and referral for smoking, alcohol, etc.
- There are no right answers; I just want to know your views.

1) Thinking of the last 5 years, how often have you visited general dental practice?

☐ 10+	☐ 5-4	☐ 2-4	☐ 1
Twice a year or more	About once a year	Less than once a year	Only this time (first visit)

2) Thinking of the last 5 years, what reasons have you had for visiting general dental practice? (tick all that apply)

☐ Check-up	☐ Follow-up	☐ Pain / Emergency	☐ Scaling/ polishing (oral hygiene)	☐ Other

Other, specify: _____

10. GENERAL AWARENESS AND RISKS

1) Have you heard of mouth cancer?

☐ Yes ☐ No

Prompts: Where have you heard? What have you heard? e.g. from dental team, any history- you or in family, social media, or other.

If mouth cancer patient- what their case is- how and when detected, referral and treatment?

2) Do you know what causes mouth cancer?

Overall how much do you know about causes for mouth cancer?
Prompts: Smoking/ alcohol/ other form of tobacco/ age/ gender/ SES/ family history
Where have you heard? Who told you? e.g. dental team, social media, or other

☐	☐	☐	☐	☐
No knowledge 1	Slight/ little knowledge 2	Some knowledge 3	Good knowledge 4	Very good knowledge 5

11. EXAMINATION

1) **Has anyone from the dental team checked you for mouth cancer - inside the mouth (intra oral)?**
Prompts: retracting your cheek, pulling your lower lip to check the inner side of your lip, using gauze to grasp the tip of your tongue and look at the back and the side of the tongue

Every visit or sometimes?

Do you know you could be checked for mouth cancer by dental team?

2) Has anyone from the dental team checked you for mouth cancer - neck area (extra oral)?

Prompts: did a member from a dental team palpate your face, ears, and neck area with their hands

Every visit or sometimes?

3) If no to 1) or 2), would you be happy to be examined during your appointment?

If no, why not?

4) If dental team checked, did they tell you it was a "mouth cancer check"?

How would you feel about dental team using the term "mouth cancer check" while examining you?

Prompts: why or why not?

☐	☐	☐	☐	☐
Not happy at all 1	Not happy 2	Not sure 3	Happy 4	Very happy 5

5) We're conducting interviews in Oman as well: there are some cultural issues like- a male dentist checking a female patient, or vice-versa. What are your thoughts on this?

Prompts: Would you be happy to be examined by female/male dentist? If not, why?

12. PREVENTION (ADVICE/ REFERRAL)

a. <u>Smoking or other form of tobacco</u> (views and experiences of current/previous visits)

1) May I ask, are you a smoker?

☐ Never ☐ Current ☐ Ex-smoker

2) Do you use any other tobacco products?

☐ Yes ☐ No

If yes, which ones? E.g. pipe tobacco, cigars, chewing tobacco, E-cigarettes or other?

3) Has your dental team ever asked about your smoking status?

☐ Yes ☐ No

4) If smoker, have you ever thought about quitting?

☐ Yes ☐ No

Prompts: why or why not?

5) If smoker (current or ex): has your dental team ever offered advice / counselling on smoking (or other form of tobacco)?

☐ Yes ☐ No

Prompts: What did they say? Why you had that conversation? What context- mouth cancer, gum disease, staining, or other?
What advice do you remember?

- Harmful effects of smoking or benefits of quitting
- Any leaflets or educational materials
- Referral: cessation/counselling services or to pharmacist or provided smoking quit line number or medicines for quitting (NRT- gum, patches, and lozenges), etc.
- Did it help?
- Any follow-up (by phone calls or next appointment)

6) How do you feel about receiving smoking advice from:

□ Dental team within the practice (as part of consultation)
□ Or dentist referring you to cessation services or GP

Prompts: why or why not?

7) If current smoker, how would you feel about receiving brief advice up to 5 minutes from your dental team about quitting smoking?

Prompts: why or why not? What would help?

☐ Not happy at all 1 ☐ Not happy 2 ☐ Not sure 3 ☐ Happy 4 ☐ Very happy 5

b. <u>Alcohol</u> (views and experiences of current/previous visits)

1) May I ask, how often do you have a drink containing alcohol?

☐ Never ☐ Monthly or less ☐ 2–4 times per month ☐ 2–3 times per week ☐ 4+ times per week

2) Has your dental team ever asked you about drinking?

☐ Yes ☐ No

Prompts: If yes, did they use a tool or questionnaire to ask about alcohol?

3) Has your dental team ever offered any advice / counselling on alcohol?

☐ Yes ☐ No

Prompts: What did they say? Why you had that conversation? What context- mouth cancer, gum disease, trauma, or other?
What advice do you remember?

- Harmful effects of alcohol or benefits of moderating/ quitting
- Talked about safe drinking levels
- Any leaflets or educational materials
- Referral: cessation/counselling services or to pharmacist or provided quit line number, etc.
- Did it help?
- Any follow-up (by phone calls or next appointment)

4) How do you feel about receiving alcohol advice from:

□ Dental team within the practice (as part of consultation)
□ Or dentist referring you to cessation services or GP

Prompts: why or why not?

5) How would you feel about receiving brief advice up to 5 minutes from your dental team about alcohol?

Prompts: why or why not? What would help?

☐	☐	☐	☐	☐
Not happy at all 1	Not happy 2	Not sure 3	Happy 4	Very happy 5

13. POTENTIAL INTERVENTION

1) How would you feel about dentist telling you a risk score as high, medium or low for mouth cancer based on your personal information- e.g. smoking, alcohol, age, years of education, family history?

Prompts: Which would then lead onto a mouth cancer check and then appropriate smoking/alcohol behavioural counselling?

Do you think people will be happy to provide this information correctly to their dental team?

2) How would you feel or how happy would you be about having a risk score/ categorisation?

Prompts: why or why not?

☐	☐	☐	☐	☐
Not happy at all 1	Not happy 2	Not sure 3	Happy 4	Very happy 5

3) How would you feel if "mouth cancer check" was given following a discussion about mouth cancer risks?

Prompts: why or why not?

☐	☐	☐	☐	☐
Not happy at all 1	Not happy 2	Not sure 3	Happy 4	Very happy 5

4) Would you be happy to enter this information onto a paper form or online form or an app at the practice or would you be happy for someone in the dental team to ask you these directly?

Prompts: self-completion in waiting room? Or go over with dental team- as part of consultation?

5) Which would you prefer to receive risk categorisation as:

☐ Traffic light - Red (for high), Amber (for medium), Green (for low)
☐ High, medium and low
☐ As a number or percentage score or in times
e.g. chance of getting cancer in 5 or 10 or 20 years

6) Would you be happy to visit the dentist for a mouth cancer check more often (3-6 months) if dentist told you were at higher risk?

Prompts: people who smoke or drink alcohol should come every 3 to 6 months for check-up than those who don't smoke or drink- to make sure nothing is wrong.

7) Would you be happy to visit the dentist less often (12months or 2 yearly) if dentist told you were considered at low risk?

Prompts: Note and you had no other dental problems and the dentist considered your teeth, gums and mouth healthy.

14. OTHER

1) Is there anything else re mouth cancer check, brief advice and referral you wish to say?

15. <u>GENERAL BACKGROUND INFORMATION</u> (so we cover a range of patients, we'll not disclose any information)

1) What year were you born? _____

2) Gender:
- Male
- Female

3) What is your ethnic group?

White	☐Scottish	☐Northern Irish	☐Gypsy/ traveler
	☐English	☐British	☐Polish
	☐Welsh	☐Irish	☐White Other
Mixed			

Asian, Asian Scottish or Asian British	☐Pakistani, Pakistani Scottish or Pakistani British	☐Bangladeshi, Bangladeshi Scottish or Bangladeshi British	☐Chinese, Chinese Scottish or Chinese British
	☐Indian, Indian Scottish or Indian British		☐Other
African, Caribbean or Black	☐African, African Scottish or African British	☐Caribbean, Caribbean Scottish or Caribbean British	☐Black, Black Scottish or Black British
			☐Other
Any other ethnicity			

4) For Oman: Nationality:

☐ Omani ☐ Non-Omani _____

5) **Where do you live now:** Governorate _____ Province_____

6) Are you currently working?

☐ Yes ☐ No

If yes, what is your current occupation/job? _____

7) What is your postcode? _____

(It will not be used to look up your address or to identify you in any way. We are asking this so we get people from different parts of Scotland.)

Thank you very much. I appreciate the time you took for this interview.

Appendix 5.2: MVLS Approval for Patients Interview

University of Glasgow | College of Medical, Veterinary & Life Sciences

25th January 2017

Dear Dr Ross

MVLS College Ethics Committee

Project Title: Oral cancer risk assessment, examination and prevention: patients¿ views and experiences to develop an intervention to implement best practice and clinical guidelines in general dental practices in Scotland and Sultanate of Oman

Project No: 200160052

The College Ethics Committee has reviewed your application and has agreed that there is no objection on ethical grounds to the proposed study. It is happy therefore to approve the project, subject to the following conditions:

- The project and in particular the wording of the Participant information Sheet is approved by the NHS REC
- The project is approved by the relevant Omani ethics committee
- Project end date: 31 March 2018
- The data should be held securely for a period of ten years after the completion of the research project, or for longer if specified by the research funder or sponsor, in accordance with the University's Code of Good Practice in Research: (http://www.gla.ac.uk/media/media_227599_en.pdf)
- The research should be carried out only on the sites, and/or with the groups defined in the application.
- Any proposed changes in the protocol should be submitted for reassessment, except when it is necessary to change the protocol to eliminate hazard to the subjects or where the change involves only the administrative aspects of the project. The Ethics Committee should be informed of any such changes.
- You should submit a short end of study report to the Ethics Committee within 3 months of completion.

Yours sincerely

Dorothy McKeegan

Dr Dorothy McKeegan
College Ethics Officer

Dr Dorothy McKeegan

Senior Lecturer

R303 Level 3
Institute of Biodiversity Animal Health and Comparative Medicine
Jarrett Building
Glasgow G61 1QH Tel: 0141 330 5712

Appendix 5.3: MOH Oman Approval (Patients Intreview)

Sultanate of Oman
Ministry of Health
Directorate General of Planning and Studies

سلطنة عمان
وزارة الصحة
المديرية العامة للتخطيط والدراسات

Ref. MoH/DGPS/CSR/PROPOSAL_ APPROVED /9/2017 الرقم:

Date 14.3.2017 التاريخ:

المرفق:

Naeema Al Bulushi
Principal Investigator

Study Title : **"Oral (mouth) cancer risk assessment, examination and prevention: patients' views and experiences to develop an intervention to implement best practice and clinical guidelines in general dental practices in Scotland and Sultanate of Oman"**

After compliments

We are pleased to inform you that your research proposal **"Oral (mouth) cancer risk assessment, examination and prevention: patients' views and experiences to develop an intervention to implement best practice and clinical guidelines in general dental practices in Scotland and Sultanate of Oman "** has been approved by Research and Ethical Review & Approve Committee, Ministry of Health.

Regards,

Dr. Ahmed Mohamed Al Qasmi
Director General of Planning and Studies
Chairman, Research and Ethical Review and Approve Committee
Ministry of Health, Sultanate of Oman.

Cc
Day file

P.O. Box : 393, Postal Code: 100, Muscat, Tel.: 24601161, Fax : 24696533 ص.ب : ٣٩٣ الرمز البريدي : ١٠٠ ، مسقط ، هاتف: ٢٤٦٠١١٦١، فاكس : ٢٤٦٩٦٥٣٣

Appendix 5.4: NHS Approval

NHS
Health Research Authority
South Central - Berkshire B Research Ethics Committee
Whitefriars
Level 3, Block B
Lewins Mead
Bristol
BS1 2NT

24 January 2017

Prof David Conway
Level 8, Glasgow Dental Hospital and School
378 Sauchiehall Street
Glasgow
G2 3JZ

Dear Prof Conway

Study title:	**Oral (mouth) cancer risk assessment, examination and prevention: patients' views and experiences to develop an intervention to implement best practice and clinical guidelines in general dental practices in Scotland and Sultanate of Oman**
REC reference:	**17/SC/0054**
Protocol number:	**N/A**
IRAS project ID:	**218059**

The Proportionate Review Sub-committee of the South Central - Berkshire B Research Ethics Committee reviewed the above application on 24 January 2017.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact hra.studyregistration@nhs.net outlining the reasons for your request. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Ethical opinion

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of

the study.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA Approval (England)/ NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion").

Approved documents

The documents reviewed and approved were:

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Evidence of Sponsor insurance]	Version 2.0	12 December 2016
Interview schedules or topic guides for participants [Interview schedule]	Version 2.0	12 December 2016
IRAS Checklist XML [Checklist_13012017]		13 January 2017
Letter from funder [Letter re support for PhD studentship]	Version 2.0	12 December 2016
Other [CV supervisor]	Version 2.0	12 December 2016
Other [PhD award letter]	Version 2.0	12 December 2016
Other [CV supervisor]	Version 2.0	12 December 2016
Other [CV student2]	Version 2.0	12 December 2016
Participant consent form [Participant consent form]	Version 2.0	12 December 2016
Participant information sheet (PIS) [Participant information sheet]	Version 2.0	12 December 2016
REC Application Form [REC_Form_13012017]		13 January 2017
Research protocol or project proposal [Research Protocol]	Version 2.0	12 December 2016
Summary CV for Chief Investigator (CI) [CV Chief Investigator]	Version 2.0	12 December 2016
Summary CV for student [CV student]	Version 2.0	12 December 2016
Summary CV for supervisor (student research) [CV supervisor]	Version 2.0	12 December 2016

Membership of the Proportionate Review Sub-Committee

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

There were no declarations of interest.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee's best wishes for the success of this project.

17/SC/0054	Please quote this number on all correspondence

Yours sincerely

pp. L Roberts.

Dr John Sheridan
Chair

Email: nrescommittee.southcentral-berkshireb@nhs.net

Copy to: *Miss Emma-Jane Gault*
Mrs Kayleigh McKenna, Senior Research Administrator - PR Team, NHS Greater Glasgow and Clyde

South Central - Berkshire B Research Ethics Committee

Attendance at PRS Sub-Committee of the REC meeting on 24 January 2017

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr John Sheridan	Consultant Toxicologist and Chemist	Yes	
Mrs Mary Sneade	Clinical Trial manager	Yes	
Miss Elena Villarreal	Clinical Trial Manager	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Lucy Roberts	REC Manager

Appendix 5.5: Clinical Research and Development Approval

Senior Research Administrator: Kayleigh McKenna
Telephone Number: 0141 232 1826
E-Mail: Kayleigh.Mckenna@ggc.scot.nhs.uk
website www.nhsggc.org.uk/rd

Clinical Research & Development
West Glasgow ACH
Dalnair Street
Glasgow G3 8SJ
Scotland, UK

26/01/2017

Professor David Conway
Glasgow Dental Hospital and School
University of Glasgow
378 Sauchiehall Street
Glasgow
G2 3JZ

NHS GG&C Board Approval

Dear Professor Conway,

Study Title:	Oral (mouth) cancer risk assessment, examination and prevention: patientsâ€™ views and experiences to develop an intervention to implement best practice and clinical guidelines in general dental practices in Scotland and Sultanate of Oman
Principal Investigator:	Professor David Conway
GG&C HB site	NHS Greater Glasgow & Clyde Dental Practices
Sponsor	NHS Greater Glasgow & Clyde
R&D reference:	GN16OD737
REC reference:	17/SC/0054
Protocol no: (including version and date)	V2.0 12/12/16

I am pleased to confirm that Greater Glasgow & Clyde Health Board is now able to grant Approval for the above study.

Conditions of Approval

1. For Clinical Trials as defined by the Medicines for Human Use Clinical Trial Regulations, 2004
   a. During the life span of the study GGHB requires the following information relating to this site
      i. Notification of any potential serious breaches.
      ii. Notification of any regulatory inspections.

It is your responsibility to ensure that all staff involved in the study at this site have the appropriate GCP training according to the GGHB GCP policy (www.nhsggc.org.uk/content/default.asp?page=s1411), evidence of such training to be filed in the site file.

2. For all studies the following information is required during their lifespan.
   a. Recruitment Numbers on a quarterly basis
   b. Any change of staff named on the original SSI form

NHS
Greater Glasgow and Clyde

c. Any amendments – Substantial or Non Substantial
d. Notification of Trial/study end including final recruitment figures
e. Final Report & Copies of Publications/Abstracts

Please add this approval to your study file as this letter may be subject to audit and monitoring.

Your personal information will be held on a secure national web-based NHS database.

I wish you every success with this research study

Yours sincerely,

Kayleigh McKenna
Senior Research Administrator

CC: S.Mathur

Appendix 5.6: Letter of Access for Research (Research Passport)

Senior Research Administrator: Mrs Kayleigh McKenna
Telephone Number: 0141 232 1826
E-Mail: Kayleigh.mckenna@ggc.scot.nhs.uk
Website: www.nhsggc.org.uk/r&d

Research & Development
West Glasgow ACH
Dalnair Street
Glasgow G3 8SW

26 January 2017

Miss Sweta Mathur
University of Glasgow Dental School
378 Suchiehall Street
Glasgow
G2 3JZ

Dear Miss Mathur,

Letter of Access for Research

This letter confirms your right of access to conduct research through **NHS Greater Glasgow and Clyde** for the purpose and on the terms and conditions set out below. This right of access commences on **26.01.17** and ends on **31.08.18** unless terminated earlier in accordance with the clauses below.

You have a right of access to conduct such research as confirmed in writing in the letter of permission for research from this NHS organisation. Please note that you cannot start the research until the Principal Investigator for the research project has received a letter from us giving permission to conduct the project.

The information supplied about your role in research at **NHS Greater Glasgow and Clyde** has been reviewed and you do not require an honorary research contract with this NHS organisation. We are satisfied that such pre-engagement checks as we consider necessary have been carried out.

You are considered to be a legal visitor to **NHS Greater Glasgow and Clyde** premises. You are not entitled to any form of payment or access to other benefits provided by this NHS organisation to employees and this letter does not give rise to any other relationship between you and this NHS organisation, in particular that of an employee.

While undertaking research through **NHS Greater Glasgow and Clyde**, you will remain accountable to your employer **[insert employer]** but you are required to follow the reasonable instructions of **Frances McLinden** in this NHS organisation or those given on her/his behalf in relation to the terms of this right of access.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation by this NHS organisation in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

You must act in accordance with **NHS Greater Glasgow and Clyde** policies and procedures, which are available to you upon request, and the Research Governance Framework.

You are required to co-operate with **NHS Greater Glasgow and Clyde** in discharging its duties under the Health and Safety at Work etc Act 1974 and other health and safety legislation and to take reasonable care

for the health and safety of yourself and others while on **NHS Greater Glasgow and Clyde** premises. You must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of any other contract holder and you must act appropriately, responsibly and professionally at all times.

If you have a physical or mental health condition or disability which may affect your research role and which might require special adjustments to your role, if you have not already done so, you must notify your employer and the health board's HR department prior to commencing your research role at the Health board.

You are required to ensure that all information regarding patients or staff remains secure and *strictly confidential* at all times. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice (http://www.dh.gov.uk/assetRoot/04/06/92/54/04069254.pdf) and the Data Protection Act 1998. Furthermore you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

You should ensure that, where you are issued with an identity or security card, a bleep number, email or library account, keys or protective clothing, these are returned upon termination of this arrangement. Please also ensure that while on the premises you wear your ID badge at all times, or are able to prove your identity if challenged. Please note that this NHS organisation accepts no responsibility for damage to or loss of personal property.

We may terminate your right to attend at any time either by giving seven days' written notice to you or immediately without any notice if you are in breach of any of the terms or conditions described in this letter or if you commit any act that we reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to the interests and/or business of this NHS organisation or if you are convicted of any criminal offence. You must not undertake regulated activity if you are barred from such work. If you are barred from working with adults or children this letter of access is immediately terminated. Your employer will immediately withdraw you from undertaking this or any other regulated activity and you MUST stop undertaking any regulated activity immediately.

Your substantive employer is responsible for your conduct during this research project and may in the circumstances described above instigate disciplinary action against you.

NHS Greater Glasgow and Clyde will not indemnify you against any liability incurred as a result of any breach of confidentiality or breach of the Data Protection Act 1998. Any breach of the Data Protection Act 1998 may result in legal action against you and/or your substantive employer.

If your current role or involvement in research changes, or any of the information provided in your Research Passport changes, you must inform your employer through their normal procedures. You must also inform your nominated manager in this NHS organisation.

Yours sincerely,

Kayleigh McKenna
Senior Research Administrator

cc: EJ Gault (University of Glasgow)

Appendix 5.7: Consent Form (Arabic and English)

University of Glasgow | College of Medical, Veterinary & Life Sciences

رقم المشروع: 68121

استمارة موافقة

عنوان المشروع:

تحديد المخاطر و الفحوصات و الوقاية من سرطان الفم:
وجهة نظر المرضى و تجاربهم لتطوير وسائل الوقاية لتطبيق أفضل السبل المتبعة و المبادئ التوجيهية السريرية في الممارسات العامة في مجال طب الأسنان في اسكوتلندا و سلطنة عمان.

أسماء الباحث(ين):

الدكتورة/ سويتا ماثور؛ الفاضلة/ نعيمة البلوشي؛ الدكتور/ ألاستير روس؛ البروفيسور/ ديفيد كونوي؛ البروفيسورة/ لورنا ماكفيرسون؛ البروفيسور/ جون جبسون.

يرجى وضع أول حروف اسمك في المربعات

☐ أود التأكيد بأني قد قرأت و فهمت ورقة المعلومات المؤرخة أكتوبر 2016 النسخة رقم (v1.4.1) المتعلقة بالدراسة المشار إليها أعلاه وبأنه كانت لدي الفرصة لطرح الأسئلة.

☐ أنا على معرفة بأن مشاركتي هذه تعد تطوعيه و بأن لدي الحرية في الإنسحاب في أي وقت من دون اعطاء أي أسباب و من دون أي تأثير على حقوقي القانونية.

☐ لقد منحت موافقتى على التسجيل الصوتي للمقابلة التي ستتم معي.

☐ اوافق على المشاركة في الدراسة المشار إليها أعلاه.

_____	_____	_____
اسم المريض	التاريخ	التوقيع
_____	_____	_____
اسم الشخص الحاصل على الموافقة (اذا كان مختلفا عن الباحث)	التاريخ	التوقيع
_____	_____	_____
الباحث	التاريخ	التوقيع

(نسخة للباحث ;نسخة للمريض)

University of Glasgow | College of Medical, Veterinary & Life Sciences

Project Number: 169392-01

CONSENT FORM

Title of Project:
Oral (mouth) cancer risk assessment, examination and prevention: patients' views and experiences to develop an intervention to implement best practice and clinical guidelines in general dental practices in Scotland and Sultanate of Oman

Name of Researcher(s):
Ms Sweta Mathur; Mrs Naeema Al Bulushi; Dr Alastair Ross; Prof David Conway; Prof Lorna Macpherson; Prof John Gibson

	Please initial box
1. I confirm that I have read the information sheet dated 21 November 2016 (Version 1.0) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	☐
3. I give my permission for the interview that I take part in to be tape-recorded.	☐
4. I agree to take part in the above study.	☐
5. I agree to be approached with opportunities to take part in further studies (if yes – please complete contact details below)	☐

_____	_____	_____
Name of subject	Date	Signature
_____	_____	_____
Name of Person taking consent	Date	Signature

Contact details: _____

(When completed: 1 for participant; 1 for researcher site file; 1 (original) to be kept in medical notes.)

Appendix 5.8: Information About the Research

University of Glasgow | College of Medical, Veterinary & Life Sciences

INFORMATION ABOUT THE RESEARCH

"Oral cancer risk assessment, examination and prevention: patients' views and experiences to develop an intervention to implement best practice and clinical guidelines in general dental practices in Scotland and the Sultanate of Oman"

Introduction

You are being invited to take part in a research study. Before you decide whether to take part in the study, it is important that you understand why the research is being done and what it will involve for you. Please take some time to read the following information carefully. Feel free to discuss the study with others before you decide. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

The study is a qualitative study, involving individual interview (one-to-one) to explore the views and experiences of patients attending general dental practices in Scotland and Sultanate of Oman on oral cancer risk assessment, clinical examination and preventive interventions. We want to find out the barriers and facilitators associated with oral cancer early detection and prevention in dental practices, and gather your suggestions to inform the development of an oral cancer early detection and prevention intervention package.

Why have I been chosen?

You are being asked to take part in the study because you are attending general dental practice and can inform us as to the feasibility of translation research evidence and guidelines to everyday working environments.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part, please remember that you are free to withdraw at any time and without giving a reason.

What will happen to me if I take part?

We will invite you to participate in a 15-20 minute face-to-face interview. Questions will focus on the current barriers and facilitators to oral cancer risk assessment, examination, recall interval, advice-giving and referral among patients attending general

معلومات عن البحث

"تحديد المخاطر و الفحوصات و الوقاية من سرطان الفم: وجهة نظر المرضى و تجاربهم لتطوير وسائل الوقاية لتطبيق أفضل السبل المتبعة و المبادئ التوجيهية السريرية في الممارسات العامة في مجال طب الأسنان في اسكوتلندا و سلطنة عمان."

مقدمة

أنتم مدعوون للمشاركة في دراسة بحثية. قبل أن تقرر ما إذا كنت ستشارك في هذه الدراسة، من المهم أن تفهم لماذا يجري هذا البحث وما سينطوي عليه تجاهك. يرجى أخذ بعض الوقت لقراءة المعلومات التالية بعناية. لا تتردد في مناقشة هذه الدراسة مع الآخرين قبل أن تقرر. ابلغنا إذا كان هناك أي شيء غير واضح، أو إذا كنت ترغب في مزيد من المعلومات. يرجى أخذ الوقت الكافي لتقرر ما إذا كنت ترغب في المشاركة أو لا ترغب.

ما هو غرض الدراسة؟

تعتبر هذه الدراسة نوعية حيث أنها تشمل على مقابلة فردية (واحد إلى واحد) لاستكشاف آراء وتجارب المرضى الذين يحضرون الممارسات الأسنان العامة في اسكتلندا، وسلطنة عمان في تقييم مخاطر سرطان الفم والفحص السريري والتدخلات الوقائية. نريد معرفة العقبات والتسهيلات المرتبطة بالكشف المبكر عن سرطان الفم والوقاية في ممارسات طب الأسنان، وجمع اقتراحاتكم ليسترشد بها في الكشف المبكر عن سرطان الفم ووضع حزمة التدخلات الوقائية.

لماذا تم اختياري أنا؟

لقد تم اختيارك للمشاركة في الدراسة لأنك تستخدم خدمات الممارسة العامة لطب الأسنان، وبالتالي يمكن أن توضح لنا الجدوى من أدلة البحوث والمبادئ التوجيهية لبيئات العمل اليومية.

هل أنا ملزم بالمشاركة في البحث؟

الأمر متروك لكم لاتخاذ قرار المشاركة من عدمه. إذا كنت ترغب في المشاركة، الرجاء تذكر أنك حر في الانسحاب في أي وقت ودون إبداء الأسباب.

ماذا سيحدث لي إذا كنت سأشارك في البحث؟

سوف ندعوكم للمشاركة في مقابلة وجها لوجه لمدة تتراوح بين 15-20 دقيقة. سوف تتركز الأسئلة على العقبات الحالية و التسهيلات لتقييم مخاطر سرطان الفم والفحص، والفاصل الزمني للتذكير، وإعطاء المشورة والإحالة بين المرضى الذين يحضرون ممارسات الأسنان العامة. كما نود أن نعرف وجهات نظركم بشأن الممارسة السابقة والحالية فيما يتعلق بفحص الفم والمشورة الوقائية.

dental practices. We would also like to know your views on previous and current practice in relation to oral examination and preventive advice. We will make sure that you are happy with being tape-recorded beforehand. What do I have to do? If you are happy to take part, we will arrange a mutually convenient time for the interview. If you do not want to take part, we will not contact you again. What are the possible disadvantages and risks of taking part? There are no identified risks and it is very unlikely that you will come to any harm as a result of taking part in the study. However, if you feel uncomfortable or do not wish to continue at any time, you can leave the discussion without giving any reason. What are the possible benefits of taking part? We hope the information that will be collected during this study will be useful to support implementation and sustained use of oral cancer guidance in risk assessment, examination, prevention and referral for the benefit of the public. Each face-to-face interview participant will receive _____ as an incentive? Will my taking part in this study be kept confidential? Your information will be kept strictly confidential and anonymous. You will only be identified by an ID number, and any information about you will have your name removed so that you cannot be recognized from it. The anonymized interview notes and your records will be held securely for at least 10 years at the University of Glasgow (in accordance with Medical Research Council best research practice guidelines). We will then destroy them. What will happen to the results of the research study? The results will be used to write a PhD thesis, and will be made available as scientific papers in journals and presentations at seminars and/or conferences. We can also send you a short summary of the findings if you wish. Who is organising and funding the research? The study is being conducted by the Glasgow Dental Hospital and School at the University of Glasgow. The study is funded by NHS Education for Scotland, Glasgow Dental Educational Trust, and Ministry of Health - Sultanate of Oman.	*وسوف نتأكد من إن كنت لا تمانع من تسجيل المقابلة مسبقاً.* *ما يجب القيام به؟* *إذا كنت سعيداً المشاركة، سوف نرتب وقت مناسب للطرفين لإجراء المقابلة. إذا كنت لا تريد المشاركة، سوف لن نتصل بك مرة أخرى.* *ما هي العيوب المحتملة والمخاطر نتيجة المشاركة في البحث؟* *لا توجد أية مخاطر تذكر تم تحديدها وأنه من المستبعد جداً أن تتعرض لأي ضرر نتيجة للمشاركة في الدراسة. ومع ذلك، إذا كنت تشعر بعدم الارتياح، أو لا ترغب في الاستمرار في أي وقت، يمكنك ترك المناقشة دون إبداء أي سبب.* *ما هي الفوائد المحتملة للمشاركة في البحث؟* *نأمل أن المعلومات التي سيتم جمعها خلال هذه الدراسة ستكون مفيدة لدعم تنفيذ والاستخدام المستمر للتوجيهات المتعلق بتقييم وفحص مخاطر سرطان الفم و الإحالة من أجل خدمة الصالح العام.* *سوف يحصل كل مشارك في المقابلة وجها لوجه على -------كحافز؟* *هل ستكون مشاركتي في هذه الدراسة محاطة بالسرية؟* *ستبقى المعلومات الخاصة بك سرية ومجهولة تماما. سيتم التعرف عليك فقط برقم معرف، وسيتم إزالة اسمك عن أي معلومات تتعلق بك بحيث لا يمكن أن يتم التعرف عليك من خلالها. سوف تبقي الملاحظات من المقابلة مجهولة المصدر والسجلات الخاصة بك محفوظة بشكل آمن لمدة 10 سنوات على الأقل في جامعة غلاسكو (وفقا لأفضل الممارسات للمبادئ التوجيهية للبحوث من قبل "مجلس البحوث الطبية"). وبعد انقضاء تلك الفترة سوف يتم التخلص منها.* *ماذا سيحدث لنتائج الدراسة البحثية؟* *النتائج سوف تستخدم لكتابة أطروحة دكتوراه، وستكون متاحة كورقة علمية في المجلات والعروض المقدمة في حلقات دراسية و/أو مؤتمرات. ويمكن أيضا أن نرسل لك ملخص مقتضب للنتائج إذا كنت ترغب في ذلك.* *ما هي الجهة المنظمة و الممولة للبحث؟* *يقوم بهذه الدراسة مستشفى ومدرسة غلاسكو لطب الأسنان في جامعة غلاسكو. ويتم تمويل هذه الدراسة من قبل كلا من خدمة الصحة الوطنية للتعليم لأجل اسكتلندا وصندوق غلاسكو لتعليم طب الأسنان و وزارة الصحة في سلطنة عمان.* *من الذي قام بمراجعة هذه الدراسة؟* *المشروع تمت مراجعته من قبل كلية الطب ولجنة أخلاقيات الطب البيطري وعلوم الحياة، و خدمة أخلاقيات البحوث لخدمة الصحة الوطنية لغرب اسكتلندا و اللجنة الإدارية للبحث و التطوير للنظام الصحي الوطني. كما تم أيضا تقديم مسودة الدراسة إلى اللجنة الإدارية للبحوث في مستشفى ومدرسة غلاسكو لطب الأسنان.*

Who has reviewed the study? The project has been reviewed by the College of Medicine, Veterinary and Life Sciences Ethics Committee, NHS West of Scotland Research Ethics Service (WoSRES) and NHS R&D Management committee. A study proposal has also been submitted to the Glasgow Dental Hospital and School Research Management Committee. Contact for Further Information: Please contact Dr Sweta Mathur at s.mathur.1@research.gla.ac.uk or +447778391940; Mrs Naeema Al Bulushi at n.al-bulushi.1@research.gla.ac.uk or +447494510033 (UK); +96892303333 (Oman) If you have any concerns about any aspect of this study, please contact Dr Alastair Ross at alastair.ross@gla.ac.uk or +44 141 211 9811 Thank you for taking the time to read this information.	*للحصول على مزيد من المعلومات يمكن الاتصال:* ***الدكتوره/سويتا ماثور*** s.mathur.1@research.gla.ac.uk *أو* +447778391940؛ *الفاضلة/ نعيمة البلوشي* n.al-bulushi.1@research.gla.ac.uk ***أو*** +447494510033 *(بريطانيا)؛* +96892303333 *(عمان)* *إذا كان لديك أي قلق حول أي جانب من جوانب هذه الدراسة، يرجى الإتصال بالدكتور أليستر روس في* alastair.ross@gla.ac.uk ***أو*** +44 141 211 9811 *شكرا لكم لأخذ الوقت لقراءة هذه المعلومات.*